CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date:	March 5, 2012
Reviewer:	Loretta Holmes, BSN, PharmD Division of Medication Error Prevention and Analysis (DMEPA)
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis (DMEPA)
Drug Name and Strength:	Qnasl (Beclomethasone Dipropionate) Nasal Aerosol 80 mcg per actuation
Application Type/Number:	NDA 202813
Applicant:	Teva Branded Pharmaceutical Products R&D, Inc.
OSE RCM #:	2011-3251

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CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Qnasl 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, Qnasl, acceptable in OSE Review 2011-2237, dated August 24, 2011.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches 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. For this review we used the same search criteria described in OSE Review 2011-2237. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded one new name, Q-Nol, thought to look or sound similar to Qnasl and represent a potential source of drug name confusion. Q-Nol was identified in POCA but could not be verified in any of the usual reference databases (e.g., Facts and Comparisons Online, Clinical Pharmacology Online, Micromedex, Lexicomp Online, Red Book Online, walgreens.com, etc.); therefore, no failure mode and effects analysis was conducted between Qnasl and Q-Nol.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any USAN stems in the proposed proprietary name, as of January 15, 2012.
OPDP re-reviewed the proposed name on December 15, 2011 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Qnasl, did not identify any vulnerability that would result in medication errors. Thus, DMEPA has no objection to the proprietary name, Qnasl, 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 Pulmonary, Allergy and Rheumatology Products (DPARP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE Project Manager, at 301-796-3904.

4 REFERENCES

1. Holmes, Loretta. Proprietary Name Review of Qnasl, OSE Review 2011-2237, dated August 24, 2011.

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/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?)*

   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.

5. ***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.

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/s/

LORETTA HOLMES
03/05/2012

IRENE Z CHAN
03/05/2012

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

Proprietary Name Review

Date:	August 24, 2011
Reviewer:	Loretta Holmes, BSN, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Team Leader:	Irene Z. Chan, PharmD, BCPS, Team Leader Division of Medication Error Prevention and Analysis (DMEPA)
Division Director	Carol A. Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
Drug Name:	Qnasl (Beclomethasone Dipropionate) Nasal Aerosol 80 mcg per actuation
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CONTENTS

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

DMEPA previously evaluated the proposed proprietary name, Qnaze, during the IND phase for this product (IND 101639). In OSE Review 2010-2011, dated March 10, 2011, we found Qnaze unacceptable because of potential confusion with the currently marketed name, Avage. Thus, the Applicant submitted the name, Qnasl, to the NDA on May 27, 2011, for our evaluation. This is a 505(b)(2) application. The reference listed drug is Beconase AQ (NDA 019389).

1.2 PRODUCT INFORMATION

Qnasl is indicated for the treatment of the symptoms of seasonal and perennial allergic rhinitis in adults and adolescent patients 12 years of age and older. The recommended dosage is 320 mcg per day administered as two nasal aerosol sprays in each nostril (80 mcg per spray) once daily (maximum total daily dose of 4 nasal aerosol sprays per day).

Qnasl will be supplied as a pressurized aluminum canister inserted into a blue and white plastic nasal actuator with a built-in counter and white dust cap. Each canister contains 8.7 g of drug and excipients and provides 120 actuations after priming. Each actuation delivers 80 mcg of beclomethasone dipropionate from the nasal actuator. Qnasl has a built-in dose counter which starts at 124 (4 sprays are for priming) and counts down each time an aerosol spray is released. The correct amount of medication in each intranasal dose cannot be ensured after the counter reads 0; therefore, the device should be discarded when the counter reads 0. Qnasl should be stored at 25ºC (77ºF); excursions permitted between 15ºC and 30ºC (59ºF and 86ºF)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The United States Adopted Name (USAN) stem search conducted on August 1, 2011 identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

Qnasl begins with the letter "Q" which is a medical abbreviation that means "every".[1] However, the letter "Q" is not separated by a hyphen or space and is, thus, like any other name that begins with the letter "Q". Additionally, the "nasl" portion of the name can be pronounced like "nasal" which is the route of administration for this product (see name simulation studies, Section 2.2.3 below). Because the actual spelling is "nasl", and because this product is in fact administered nasally, we find this portion of the name acceptable; however, should the Applicant wish to expand their product line in the future to other routes of administration, the name may be determined to be misleading. DMEPA discourages incorporating the route of administration in the proprietary name because doing so could limit the use of the name should the Applicant seek a new dosage form for the product.

2.2.3 FDA Name Simulation Studies

Forty-two practitioners participated in DMEPA's prescription studies. We note that the majority of respondents in the verbal study interpreted the name as "Q-NASAL". Additionally, the majority of respondents in the outpatient written study interpreted the first letter "Q" as the letter "O". See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, June 24, 2011 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Table 1 lists the names identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines, with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Qnasl (see Appendix B).

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[1]Definition obtained from the website: http://www.medilexicon.com/medicalabbreviations.php. Accessed on August 16, 2011.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD and Other Disciplines)

Look Similar		Sound Similar		Look and Sound Similar	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Qvar	EPD Panel	Canasa	EPD Panel	(b) (4)	EPD Panel
(b) (4)	EPD Panel				
Arava	EPD Panel				
Oasis	EPD Panel				
Ornex	EPD Panel				
(b) (4)	EPD Panel				
Onsolis	EPD Panel				
Quasense	EPD Panel				
Quala	EPD Panel				
Animi-3	EPD Panel				
Ansaid	EPD Panel				
Gas-X	EPD Panel				
Sansac	EPD Panel				
Q-Acin	EPD Panel				
Orencia	EPD Panel				
O-Cal	EPD Panel				
Ocella	EPD Panel				
Os-Cal	EPD Panel				
Oxide	EPD Panel				
(b) (4)	EPD Panel				
Ovace	EPD Panel				
Avage	Primary Safety Evaluator				
Anusol	Primary Safety Evaluator				
Asacol	Primary Safety Evaluator				

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Look Similar		Sound Similar		Look and Sound Similar	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Aviane	Primary Safety Evaluator				

Our analysis of the 27 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined the 27 names will not pose a risk for confusion as described in Appendices D and E.

DMEPA communicated these findings to the Division of Pulmonary, Allergy and Rheumatology Products via e-mail on August 18, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Pulmonary, Allergy, and Rheumatology Products on August 24, 2011, they stated no additional concerns with the proposed proprietary name, Qnasl.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary name is acceptable from both a promotional and safety perspective. However, 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. Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA.

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE Project Manager, at 301-796-3904.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Qnasl, and have concluded it is acceptable at this time.

Qnasl 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 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.

4 REFERENCES

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

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

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

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

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

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

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

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

16. ***Medical Abbreviations Book***

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

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [2]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[3] The product characteristics considered for this review appears in Appendix B1 of this review.

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

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

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
	Similar spelling	Identical prefix Identical infix Identical suffix	• Names may appear similar in print or electronic media and lead to drug name

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

Look-alike		Length of the name Overlapping product characteristics	confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the

trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA

requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[4] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names 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 ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

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

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

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

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

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

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

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

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

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

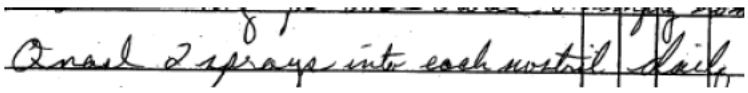
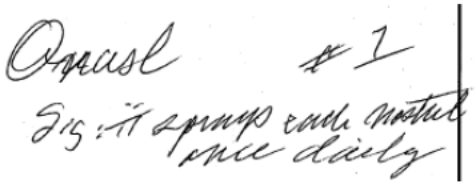
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, NAME	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'Q'	G, O	K
lower case 'q'	g, j, z	k
lower case 'n'	m, u, x, r, h, s	dn, gn, kn, mn, pn
lower case 'a'	el, ci, cl, d, o, u	any vowel
lower case 's'	G, g, n	
lower case 'l'	b,e, s, A, P, i	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Qnasl Study (Conducted on July 15, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	"Qnasl Disp #1 Two sprays into each nostril once daily"
Outpatient Prescription: 	

FDA Prescription Simulation Responses.

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
QNAIL	ANASL???	Q NASAL
QNAIL	ONASAL	Q NASAL
QNASAL	ONASE	Q NASAL
QNASAL	ONASL	QNASAL
QNASL	ONASL	Q-NASAL
QNASL	ONASL	Q-NASAL
QNASL	ONASL	Q-NASAL
QNASL	ONASL	Q-NASAL
QNASL	ONASL	Q-NASAL
QNASL	ORUASL	Q-NASAL
QNASL	OXASL	Q-NASAL
QNASL	QNASL	Q-NASAL
QNASL		Q-NASAL
QNEIL		Q-NASAL
		Q-NASAL
		QUENASIL

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

	Proprietary Name	Similarity to Qnasl	Failure preventions
1	Oasis (Glycerin) Oral Spray	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
2	Ornex (Acetaminophen and Pseudoephedrine HCl) Tablets	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.

	Proprietary Name	Similarity to Qnasl	Failure preventions
3	(b) (4)	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
4	Onsolis (Fentanyl Citrate) Buccal Tablets	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
5	Quasense (Ethinyl Estradiol and Levonorgestrel) Tablets	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
6	Animi-3 (Omega-3, Vitamin B-6, Vitamin B-12, and Folate) Capsules	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
7	Gas-X (Simethicone) Chewable Tablets	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
8	Sansac (Erythromycin) Topical Solution	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
9	Orencia (Abatacept) for Injection	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
10	Ocella (Ethinyl Estradiol and Drospirenone) Tablets	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
11	Oxide-2 (Hydrogen Peroxide) Liquid	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
12	(b) (4)	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.

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	Proprietary Name	Similarity to Qnasl	Failure preventions
	Tenofovir) Tablets		
13	Q-Acin (Aspirin and Caffeine) Tablets	Look	Name lacks sufficient orthographic or phonetic similarity to Qnasl.
14	Quala (root name) *Quala HC* (Guaifenesin, Hydrocodone Bitartrate, and Phenylephrine HCl) Syrup *Quala T* (Dextromethorphan Hydriodide, Guaifenesin, and Pseudoephrine HCl) Extended-release Tablets	Look	Quala HC and Quala T are discontinued; we were unable to identify any generic equivalent products.
			(b) (4)

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

	Proposed name: **Qnasl (Beclomethasone Dipropionate) Nasal Spray**	**Strength:** **80 mcg per actuation**	**Usual dose:** **Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
16	Qvar (Beclomethasone Dipropionate) Inhalation Aerosol Strength: 40 mcg per actuation and 80 mcg per actuation Dosage: 40 mcg to 320 mcg via oral inhalation twice daily	Orthographic: The first three letters in each name ("Qna" vs. "Qva") may look similar when written. Strength: Both products share an overlapping strength, 80 mcg per actuation. Active ingredient: Both Qnasl and Qvar contain the same active ingredient. Dosage form: Both products are aerosol type products.	Orthographic: The ending upstroke letter "l" in Qnasl may help to differentiate the names. Dose: The dose for Qvar would likely be stated in terms of the number of "puffs" or "inhalations" since it is an oral inhaler whereas the dose for Qnasl would likely be in terms of "sprays".
17	Arava (Leflunomide) Tablets Strength: 10 mg and 20 mg Dosage: 100 mg orally once daily for 3 days then 10 mg or 20 mg once daily	Orthographic: Both names contain five letters. The first two letters in each name ("Qn" vs. "Ar") may look similar when written. The third position letter "a" is identical to both names.	Orthographic: The ending letters ("sl" vs. "va") do not look similar when written. Strength: Single strength vs. 10 mg or 20 mg Additionally, Qnasl will be available in a single strength so the strength would not be required on a prescription whereas Arava is available in two strengths so the strength of Arava would need to be specified on a prescription. Route of administration: Intranasal vs. oral Dosage form: Nasal aerosol spray vs. tablets

	Proposed name: **Qnasl (Beclomethasone Dipropionate) Nasal Spray**	**Strength:** **80 mcg per actuation**	**Usual dose:** **Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
18	O-Cal root name O-Cal FA (Ascorbic Acid (Vitamin C) 90mg, Calcium Carbonate 200mg, Cholecalciferol 400IU, Cupric Sulfate 2mg, Cyanocobalamin (Vitamin B12) 12mcg, Ferrous Fumarate 27mg, Folic Acid (Vitamin B9) 1mg, Magnesium Oxide 100mg, Niacinamide 20mg, Potassium Iodide 150mcg, Pyridoxine (Vitamin B6) 4mg, Riboflavin (Vitamin B2) 3mg, Sodium Fluoride 0.5mg, Thiamine Hydrochloride (Vitamin B1) 3mg, Vitamin A Acetate 2500IU, Vitamin E Acetate 30IU, Zinc Oxide 15mg) Tablets O-Cal Prenatal (Ascorbic Acid (Vitamin C) 70mg, Beta-Carotene (Vitamin A) 2500IU, Calcium Carbonate 500mg [Calcium 200mg], Cholecalciferol 400IU, Cupric Sulfate 2mg, Cyanocobalamin (Vitamin B12) 12mcg, Dl-Alpha Tocopheryl Acetate (Vitamin E) 30IU, Ferrous Fumarate 45.5mg [Iron 15mg], Folic Acid (Vitamin B9) 1mg, Magnesium Oxide 100mg, Niacin (Vitamin B3) 17mg, Potassium Iodide 150mcg, Pyridoxine (Vitamin B6) 12mg, Riboflavin (Vitamin B2) 1.6mg, Thiamine Hydrochloride (Vitamin B1) 1.5mg, Zinc Oxide 15mg) Tablets	Orthographic: The beginning letters of the names "Q" vs. "O" may look similar when written and the two ending letters "al" are identical to both names. Strength: Qnasl and both O-Cal products are available in a single strength; therefore, the strength does not have to be specified on a prescription for any of these products.	Orthographic: The second positions letters "n" vs. "c" look different when written. The root name "O-Cal" would require that the modifier (either "FA" or "Prenatal") be specified on a prescription to indicate which product is to be dispensed. Route of administration: Intranasal vs. oral Dosage form: Nasal aerosol spray vs. tablets

	Proposed name: **Qnasl (Beclomethasone Dipropionate) Nasal Spray**	**Strength:** **80 mcg per actuation**	**Usual dose:** **Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
19	Ansaid (Flurbiprofen) Tablets Strength: 50 mg and 100 mg Dosage: 50 mg or 100 mg orally twice daily, three times per day or four times per day (maximum dose of 300 mg per day)	Orthographic: The beginning letters ("Q" vs. "A") may look similar when written. The second letter "n" is identical to both names. Both names end with an upstroke letter ("l" vs. "d").	Orthographic: The third and fourth position letters are reversed in the names ("as" vs. "sa") which help to differentiate them. Additionally, Ansaid contains the dotted letter "i" whereas Qnasl does not contain any dotted letters. Strength: Single strength vs. 50 mg and 100 mg Frequency of administration: Once daily vs. twice daily, three times per day, or four times per day Dosage form: Nasal aerosol spray vs. tablets Route of administration: Intranasal vs. oral
20	Os-Cal (Calcium Carbonate) Chewable Tablets Strength: 1250 mg Dosage: One tablet orally twice daily	Orthographic: The beginning letters ("Qn" vs. "Os") may look similar when written. Both names end with the letter "l". Strength: Both products are available in a single strength so the products could get dispensed without the strength being specified.	Orthographic: The third position letters ("a" vs. "c") do not look similar when written. Frequency of administration: Once daily vs. twice daily Dosage form: Nasal aerosol spray vs. tablets Route of administration: Intranasal vs. oral

	Proposed name: **Qnasl (Beclomethasone Dipropionate) Nasal Spray**	**Strength:** **80 mcg per actuation**	**Usual dose:** **Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
21	Ovace (Sodium Sulfacetamide) Foam Wash Strength: 10% Dosage: *Foam* Apply to the affected area(s) twice daily *Wash* Wash affected area(s) twice daily	Orthographic: The beginning letters ("Qn" vs. "Ov") may look similar when scripted. Both names contain the letter "a" in the third position. Strength: Both products are available in a single strength so the products could get dispensed without the strength being specified Directions for use: Both products may be prescribed with directions to "use as directed".	Orthographic: The fourth position letters ("s" vs. "c") do not look similar. Dosage Form: Nasal aerosol vs. foam or wash Ovace is available in multiple dosage forms so the dosage form would have to be specified on a prescription for Ovace. Frequency of administration: Once daily vs. twice daily Route of administration: Intranasal vs. topical

	Proposed name: Qnasl (Beclomethasone Dipropionate) Nasal Spray	Strength: 80 mcg per actuation	Usual dose: Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
22	Canasa (Mesalamine) Rectal Suppositories Strength: 1,000 mg Dosage: One suppository rectally once daily at bedtime	Phonetic: Both names contain three syllables which may sound similar. Strength: Both products are available in a single strength so the products could get dispensed without the strength being specified. Frequency of administration: Both products are administered once daily.	Phonetic: The names have a rhyming sound; however the first two syllables in the names sound more distinctly different ("q-NĀ-" vs. "că-NĂ-"). Dose: Two sprays vs. one suppository Dosage Form: Nasal aerosol spray vs. rectal suppository Route of administration: Intranasal vs. rectal

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	Proposed name: **Qnasl (Beclomethasone Dipropionate) Nasal Spray**	**Strength:** **80 mcg per actuation**	**Usual dose:** **Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
24	Avage (Tazarotene) Cream Strength: 0.1% Dosage: Apply a pea-sized amount to the affected area once daily at bedtime	Orthographic: The beginning letters in the names ("Qna" vs. "Ava") and the ending letters ("sl" vs. "ge") may look similar when written. Strength: Both products are available in a single strength so the products could get dispensed without the strength being specified Directions for use: Both products may be prescribed with directions to "use as directed".	Orthographic: Avage contains the downstroke letter "g" whereas Qnasl does not contain any downstroke letters. Directions for use: Spray vs. apply

	Proposed name: **Qnasl (Beclomethasone Dipropionate) Nasal Spray**	**Strength:** **80 mcg per actuation**	**Usual dose:** **Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
25	Anusol (Pramoxine) Ointment 1% Anusol (Topical Starch) Suppositories 51% Dosage: *Ointment* Apply externally to the affected area up to 5 times daily *Suppositories* Insert one suppository rectally up to 6 times daily or after each bowel movement	Orthographic: The beginning letters in the names ("Qnas" vs. "Anus") may look similar when written. The ending letter "l" is identical to both names. Strength: Both products are available in a single strength so the products could get dispensed without the strength being specified. Directions for use: Both products may be prescribed with directions to "use as directed".	Orthographic: The letter "o" in Asacol that preceded the upstroke ending letter "l" may help to differentiate the names. Route of administration: Intranasal vs. topical Dosage form: Nasal aerosol spray vs. topical ointment and suppositories Directions for use: Spray vs. apply or insert Status: The name Anusol has been changed to Tucks for both the hemorrhoidal ointment and suppositories.

	Proposed name: **Qnasl (Beclomethasone Dipropionate) Nasal Spray**	**Strength:** **80 mcg per actuation**	**Usual dose:** **Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
26	Asacol (Mesalamine) Delayed-release Tablets Strength: 400 mg Dosage: 800 mg (2 tablets) orally three times per day	Orthographic: The beginning letters in both names ("Qn" vs. "As") may look similar when written. The third position letter "a" is identical to both names. Both names end with the letter "l". Strength: Both products are available in a single strength so the products could get dispensed without the strength being specified. Dose: Both products can be prescribed with the dosage unit "2" (in reference to "2 sprays" or "2 tablets")	Orthographic: The fourth position letters "s" vs. "c" do not look similar when written. Frequency of administration: Once daily vs. three times per day Route of administration: Intranasal vs. oral Dosage form: Nasal aerosol spray vs. tablets

	Proposed name: **Qnasl (Beclomethasone Dipropionate) Nasal Spray**	**Strength:** **80 mcg per actuation**	**Usual dose:** **Two sprays (160 mcg) into each nostril once daily (total daily dose 320 mcg)**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
27	Aviane (Ethinyl Estradiol 0.02 mg and Levonorgestrel 0.1 mg) Tablets Dosage: One tablet orally once daily	Orthographic: The beginning letters in both names ("Qn" vs. "Av") and the ending letters ("asl" vs. "ane") may look similar when scripted. Strength: Both products are available in a single strength so the products could get dispensed without the strength being specified. Frequency of administration: Both products are administered once daily. Directions for use: Both products may be prescribed with directions to "use as directed".	Orthographic: Aviane contains the dotted letter "i" whereas Qnasl does not contain any dotted letters which may help to differentiate the names. Dosage form: Nasal aerosol spray vs. tablets Route of administration: Intranasal vs. oral

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/s/

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08/24/2011

CAROL A HOLQUIST
08/25/2011