CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205488Orig1s000

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

Memo for Proprietary Name - Natesto

Date:	May 7, 2014
Reviewer:	Lisa Vo Khosla, PharmD, M.H.A., Team Leader Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Natesto (Testosterone) Nasal Gel 5.5 mg of testosterone per actuation
Application Type/Number:	NDA 205488
Applicant/Sponsor:	Trimel BioPharma SRL

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

DMEPA found the proposed name, Natesto, acceptable in OSE Review # 2013-957 and #2013-1182 dated July 11, 2013. In this review we indicated the proposed proprietary name must be re-reviewed prior to approval of the NDA. However, DMEPA no longer re-reviews proposed proprietary names within 90 days of the anticipated application approval, unless there is a change in the proposed product characteristics.

Since none of the proposed product characteristics were altered, our conclusion that the proposed proprietary name is acceptable has not changed since the aforementioned review. DMEPA has no objection to the proprietary name, Natesto, for this product at this time.

If you have further questions or need clarifications, please contact Shawnetta Jackson, OSE project manager, at 301-796-4952.

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/s/

LISA V KHOSLA
05/07/2014

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

Proprietary Name Review

Date:	July 11, 2013
Reviewer:	Manizheh Siahpoushan, PharmD Division of Medication Error Prevention and Analysis
Acting Team Leader:	James Schlick, RPh, MBA Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Natesto (Testosterone) Intranasal Gel 5.5 mg of testosterone in 122.5 mg of gel per actuation
Application Type/Number:	IND 070512 and NDA 205488
Sponsor:	Trimel Biopharma Inc.
OSE RCM #:	2013-957 and 2013-1182

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Natesto, 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

The first proposed proprietary name, CompleoTRT was found unacceptable in OSE Review #2012-1947 dated September 4, 2012. OPDP determined the proposed name was promotional because it implied superiority over other testosterone drug products and was overly fanciful. The Sponsor submitted the proposed proprietary name, Natesto on April 3, 2013 under IND 070512. Subsequent to the IND submission, the name, Natesto, was submitted under NDA 205488 on May 15, 2013 for evaluation by DMEPA.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 3, 2013 (IND 070512) and May 15, 2013 (NDA 205488) proprietary name submissions. The product characteristics submitted in the May 15, 2013 (NDA 205488) submission did not change from the April 3, 2013 (IND) submission.

- Active Ingredient: Testosterone
- Indication of Use: Replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).
- Route of Administration: Intranasal
- Dosage Form: Gel
- Strength: 5.5 mg per actuation (as a 4.5% testosterone gel)
- Dose and Frequency: The recommended starting dose is 11 mg of testosterone applied intranasally twice daily (b) (4)
- How Supplied and Packaging Configuration: Multiple dose dispenser inherent with a metered dose pump. Each multiple dose dispenser contains 11 gram of gel dispensed as 60 metered pump actuations. One pump actuation delivers 5.5 mg of testosterone in 122.5 mg of gel. (b) (4) The product will not be supplied in any physician samples or starter packs.
- Storage: Controlled Room Temperature

- Container and Closure Systems: Product is supplied in a [redacted] (b) (4), multi-dose, metered pump container. The containers are supplied [redacted] (b) (4) with cap attached.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Reproductive and Urologic Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The April 25, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Natesto, has no derivation. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Seventy-seven practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did they appear or sound similar to a currently marketed U.S. product or any products in the pipeline. Fifty prescription study participants (15 outpatient, 10 voice, and 25 inpatient) interpreted the name correctly as Natesto. Eight outpatient prescription study participants misinterpreted the name as Naxesto. Ten voice prescription study participants misinterpreted the name incorrectly as the following: Netesto (#6), Nitesto, Nonasto, and Notesto (#2). We have considered these variations in our look-alike and sound-alike searches and analysis (See Appendix B). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 6, 2013 e-mail, the Division of Reproductive and Urologic Products (DRUP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

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

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Fortesta	PR, EPD	Lunesta	EPD	Medent	EPD
Metanx	EPD	Metastron	EPD	Mitrolan	EPD
Motofen	EPD	Naltrexone	EPD	Namenda	EPD
NataChew	EPD	Natacyn	EPD	Natazia	PR, EPD
Natelle	PR, EPD	Natrecor	EPD	Natroba	PR, EPD
NeoTect	EPD	Nestabs	EPD	Neudexta	PR, EPD
Neulasta	PR, EPD	Nilandron	EPD	Nitrostat	EPD
Noludar	EPD	Noxafil	EPD	Nutralox	EPD
Nutrifac ZX	EPD	Nutri-Tab OB	EPD	Refacto	EPD
Salactic Film	EPD	Solesta	EPD	Sufenta	EPD
Sutent	EPD	Testoderm	EPD	Sotret	PR
Zotex-C	EPD	Zoto-HC	EPD	Silactin	EPD
Relister	PR				

Our analysis of the 37 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 37 names will not pose a risk for confusion as described in Appendices D through E.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Reproductive and Urologic Products via e-mail on May 21, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Reproductive and Urologic Products on May 22, 2013, they stated no additional concerns with the proposed proprietary name, Natesto.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Shawnetta Jackson, OSE project manager, at 301-796-4952.

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your April 3, 2013 and May 15, 2013 submissions are altered, the name must be resubmitted for review

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

18. ***Rx List (www.rxlist.com)***

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

19. ***Dogpile (www.dogpile.com)***

    Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. ***Natural Standard (http://www.naturalstandard.com)***

    Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [1]

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

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

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

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

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2]

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

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

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

Type of Similarity	**Considerations when Searching the Databases**		
	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/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 Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

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

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

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

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names 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. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

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

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

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

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

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

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Natesto	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'N'	M, V, U, W, H, R	DN, GN, KN, MN, PN, M
Lower case 'n'	t, x, j, b, z, l, s	dn, gn, kn, mn, pn, m
Lower case 'a'	o, u, c, e, er, ir, el, ei, ci, cl, d	Any vowel
Lower case 't'	f, l, l, r, x, A	D, f, p, pt, v
Lower case 'e'	a, i, l, o, u, P, c	Any vowel
Lower case 's'	a, v, r, z, n, g, 5	C, ce, es, sc, ss, x, z
Lower case 'o'	a, c, e, u	Oh
Letter Strings		
Na	Nir, Mir, Ner, Mer, Vir, Ver, Uli, Ulr	
Te	b, h, k	
Es	U	
To	b, k, h	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Natesto Study (Conducted on 5/3/13)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Natesto 1 pump in each nostril BID	Natesto Use as directed #1 carton
Outpatient Prescription: Natesto #1 carton UAD	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

190 People Received Study
77 People Responded

Study Name: Natesto

Total	30	20	27	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
MATESTO	0	0	1	1
NALESTO	3	0	0	3
NATESTO	15	10	25	50
NATESTO CARTON	1	0	0	1
NAXESTO	8	0	0	8
NAXESTO #1	1	0	0	1
NETESTO	1	6	0	7
NEXESTO	1	0	0	1
NITESTO	0	1	0	1
NONASTO	0	1	0	1
NOTESTO	0	2	1	3

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

No.	Proprietary Name	Active Ingredient	Similarity to Natesto	Failure preventions
1.	Testoderm	Testosterone	Look	The name pair has sufficient orthographic differences.
2.	Zoto-HC	Chlorooxylenol, Hydrocortisone, Pramoxine Hydrochloride	Look	The name pair has sufficient orthographic differences.
3.	Silactin	Chlorpheniramine and Phenylpropanolamine	Look	The name was identified in the Walgreens drug database, however, no dosing information could be found in any of the available databases for this product name.
4.	Naltrexone	Established name for Revia and Vivitrol	Look	The name pair has sufficient orthographic differences.
5.	Mitrolan	Polycarbophil Calcium	Look	The name was identified in the Walgreens drug database. However, no dosing information could be found in any of the available databases for this product name. Additionally, the name pair has sufficient orthographic differences.
6.	Noludar	Methyprylon	Look	Application withdrawn by the Federal Register effective 4/26/96 not for safety reasons. No information on this product could be found in any of the available databases.

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

No.	**Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation** **Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily.** (b) (4)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Natroba (Spinosad) Topical Suspension, 0.9% Usual Dose: Apply topically to dry scalp and hair using only the amount needed to cover the scalp and hair, rinse off with warm water after 10 minutes. Repeat treatment if live lice are seen 7 days after first treatment.	Orthographic: Both names share the same shape and length (seven letters), beginning letter string 'Nat-', ending letter 'a', and similar scripted upstrokes in the sixth position of each name 't' vs. 'b' Strength: Single strength	Orthographic: The letter string 'es' does not appear similar to the letter string 'ro' and can help differentiate Natesto and Natroba when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. one application

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	Fortesta (Testosterone) Gel 10 mg of testosterone per 0.5 gram of gel per actuation Usual Dose: Starting dose is 40 mg (4 pump actuations) topically once daily in the morning.	Orthographic: Both names share similar shapes and lengths (seven vs. eight letters), letter string '-test-' followed by similar scripted ending round vowel letters 'o' vs.'a', and similar scripted round vowels 'a' vs. 'o' in the second position of each name. Dosage Form: Gel Strength: Single strength Possible Partial Overlap in the Usual Dose: Pump actuations (two vs. four)	Orthographic: The beginning letter 'N' does not appear similar to the beginning letter 'F' and can help differentiate Natesto and Fortesta when scripted.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
3.	Medent DM (Dextromethorphan Hydrobromide, Guaifenesin, Pseudoephedrine Hydrochloride) Extended-release Tablets 30 mg/800 mg/60 mg Medent DMI (Dextromethorphan Hydrobromide, Guaifenesin, Pseudoephedrine Hydrochloride) Tablets 20 mg/400 mg/60 mg Medent LDI (Guaifenesin and Pseudoephedrine Hydrochloride) Tablets 400 mg/60 mg Medent PEI (Guifenesin and Phenylephrine Hydrochloride) Tablets, 400 mg/10 mg Usual Dose: Depending on the product, one or two tablets every 12 or 24 hours (not to exceed 2 or 4 tablets in 24 hours).	Orthographic: If the modifiers are excluded, both names share similar lengths (seven vs. six letters), share similar scripted beginning letter strings 'Na-' vs. 'Me-' followed by an upstroke ('t' vs. 'd'), similar scripted letter strings '-es-' vs. '-en-', and a sixth position upstroke 't'. Possible Overlap in the frequency of Administration: Twice daily	Orthographic: The ending letter 'o' in Natesto provides a different shape for this name and can help differentiate the root name, Medent, from Natesto when scripted. Additionally, the modifiers, DM, DMI, LDI, or PEI would have to be included with the root name, Medent to complete a prescription order. Therefore the risk of name confusion between the two product names is minimized.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
4.	Metanx (Mecobalamin, Pyridoxal-5-Phospate (Vit B6), Levomefoalte Calcium) Tablets, 2 mg/35 mg/3 mg Usual Dose: One tablet orally twice daily for nutritional supplementation to aid in the management of diabetic neuropathy.	Orthographic: Both names share similar lengths (seven vs. six letters), similar scripted beginning letter strings 'Na-' vs. 'Me-', a third position upstroke letter 't' followed by similar scripted letter strings '-est-' vs. '-anx'. Strength: Single strength Overlap in the Frequency of Administration: Twice daily	Orthographic: The extra ending letter 'o' in Natesto provides a different shape for this name and can help differentiate Natesto and Metanx when scripted.
5.	Metastron (Strontium-89 Chlordie) Injection, 1 mCi/mL (4 mL) [37 megabecquerel per mL] Usual Dose: 148 megabecquerel (4 millicurie) intravenously or 1.5 to 2.2 megabecquerel (40 to 60 microcurie) per kg	Orthographic: Both names share similar scripted beginning letter strings 'Na-' vs. 'Me-', a third position upstroke letter 't' followed by similar scripted letter strings in each name '-est-' vs. '-ast-'. Strength: Single strength	Orthographic: The extra ending letter string '-on' in Metastron provides a longer appearance for this name and can help differentiate Natesto and Metastron when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. 148 megabecquerel (4 millicurie) intravenously or 1.5 to 2.2 megabecquerel (40 to 60 microcurie) per kg with no overlap

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
6.	Motofen (Atropine Sulfate, Difenoxin Hydrochloride) Tablets 0.025 mg/1 mg Usual Dose: Initially, two tablets orally, then one tablet after each lose stool or every 3 to 4 hours as needed. Maximum of eight tablets in any 24 hour period. Treatment should not extend beyond 48 hours.	Orthographic: Both name share the same length (seven letters), similar scripted beginning letter strings 'Na-' vs. 'Mo-', a third position upstroke letter 't' followed by similar scripted round vowel letters 'e' vs. 'o', and similar scripted letter strings in similar positions of each name '-to' vs. '-fe-'. Strength: Single strength Possible Partial Overlap in the Usual Dose: Two (pump actuations vs. tablets)	Orthographic: The fifth position letter 's' in Natesto and the ending letter 'n' in Motofen provide different shapes for each name and can help differentiate Natesto and Motofen when scripted.
7.	NataChew (Prenatal Multivitamin with Iron) Tablets Usual Dose: One tablet orally once daily.	Orthographic: Both names share the beginning letter string 'Nat-' followed by similar scripted letter strings '-esto' vs. '-ache-'. Strength: Single strength	Orthographic: The extra ending letter 'w' in Natachew provides a longer appearance for this name and can help differentiate Natesto and Natachew when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. one tablet

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
8.	Natacyn (Natamycin) Ophthalmic Suspension, 5% Usual Dose: Instill one drop topically into the conjunctival sac every one to two hours for the treatment of fungal keratitis. Or instill one drop topically into conjunctival sac every four to six hours for the treatment of fungal blepharitis and fungal conjunctivitis.	Orthographic: Both names share the same length (seven letters), beginning letter string 'Nat-' followed by similar scripted letter strings '-es-' vs. '-ac-'. Strength: Single strength	Orthographic: The ending letter string '-to' in Natesto does not appear similar to the ending letter string '-yn' in Natacyn and can help differentiate Natesto and Natacyn when scripted. Frequency of Administration: Twice or three times daily vs. every one to two or every four to six hours. Usual Dose: Two pump actuations (or 11 mg) vs. one drop
9.	Natazia (Estradiol Valerate, Estradiol Valerate, Estradiol Valerate, Dienogest, Estraiol Valerate, Dienogest) Tablets 1mg/2 mg/2 mg/2 mg/3 mg/ 3 mg Usual Dose: One tablet orally once daily.	Orthographic: Both names share the same length (seven letters), beginning letter string 'Nat-' followed by similar scripted letter strings in each name '-es-' vs. '-az-', and similar scripted ending round vowel letters 'o' vs. 'a'. Strength: Single strength	Orthographic: The upstroke 't' in Natazia does not appear similar to the skinny letter 'i' in Natazia and can help differentiate Natesto and Natazia when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. one tablet.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
10.	Natelle (Prenatal Multivitamin and Multimineral with Iron) Tablets Usual Dose: One tablet orally once daily.	Orthographic: Both names share the same length (seven letters), beginning letter string 'Nate-' and similar scripted ending round vowel letters 'o' vs. 'e'. Strength: Single strength	Orthographic: The letter stirng '-ll-' in Natelle does not appear similar to the letter string '-st-' in Natesto and can help differentiate Natesto and Natelle when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. one t ablet.
11.	Natrecor (Nesiritide) Injection 1.5 mg Usual Dose: The approved initial dose is 2 mcg/kg as an intravenous bolus, followed by a continuous infusion of 0.01 mcg/kg/min intravenously.	Orthographic: Both names share the beginning letter string 'Nat-' and similar scripted letter strings in similar positions of each name '-es-' vs. '-ec-'. Strength: Single strength Possible Partial Overlap in the Usual Dose: The 11 mg dose in Natesto may be confused with an achievable dose of 110 mcg for a 55 kg patient (2 mcg/kg) especially if the 11 mg dose of testosterone is scripted with a trailing zero (i.e., 11.0 mg).	Orthographic: The ending letter string '-to' in Natesto (vs. the ending letter string '-or' in Natrecor) provides a different shape for this name and can help differentiate Natesto and Natrecor when scripted. Additionally, the extra fourth position letter 'r' in Natrecor provides a longer appearance for this name

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
12.	NeoTect (Technetium Tc 99m Depreotide) Injection Usual Dose: For imaging, administer a single dose of 15 mCi to 20 mCi containing approximately 45 mcg of Technetium Tc 99 m radiolabeled Depreotide peptide	Orthographic: Both names share the same length (seven letters), beginning letter 'N' followed by similar scripted round vowel letters 'a' vs. 'e' in each name, and similar scripted letter strings in similar positions of each name '-test-' vs. '-tect'. Strength: Single strength	Orthographic: The ending letter 'o' in Natesto and the third position letter 'o' between the upstrokes 'N' and 't' in NeoTect (vs. no letter 'o' between the upstrokes 'N' and 't' in Natesto) provide different shapes for each name and can help differentiate Natesto and NeoTect when scripted. Usual Dose: One pump actuation (or 11 mg) vs. a single dose of 15 mCi to 20 mCi with no numerical overlap between the two products.
13.	Nestabs (Prenatal Multivitamin and Multimineral) Tablets Usual Dose: One tablet orally once daily.	Orthographic: Both names share the same length (seven letters), beginning letter 'N' followed by similar scripted round vowel letters 'a' vs. 'e', similar scripted letter strings in similar positions of each name '-te-' vs. '-ta-', a sixth position upstroke in the sixth position of each name ('t' vs. 'b'), and similar scripted ending letters 'o' vs. 's'. Strength: Single strength	Orthographic: The fifth position letter 's' in Natesto and the third position letter 's' in Nestabs provide different lengths for the letter strings between the upstrokes 't' and 't' in Natesto (vs. 't' and 'b' in Nestabs) and between the upstrokes 'N' and 't' in Nestabs (vs. 'N' and 't' in Natesto), respectively and can help differentiate Natesto and Nestabs when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. one tablet.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
14.	Nuedexta (Dextromethorphan Hydrobromide and Quinidine Sulfate) Capsules 20 mg/10 mg Usual Dose: To start, one capsule orally daily for 7 days, then one capsule every twelve hours.	Orthographic: Both names share the beginning letter 'N' followed by similar scripted letters 'a' vs. 'u' in each name and similar scripted ending letter strings '-testo' vs. '-dexta'. Strength: Single strength Possible Overlap in the Frequency of Administration: Twice daily	Orthographic: The third position extra letter 'e' in Nuedexta along with the round portion of the letter 'd' in this name provide a longer length between the upstrokes 'N' and 'd' in Nuedexta (vs. the length between the upstrokes 'N' and 't' in Natesto) and can help differentiate Natesto and Nuedexta when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. one capsule
15.	Neulasta (Pegfilgranstim) Injection 6 mg per 0.6 mL Usual Dose: 6 mg subcutaneously once per chemotherapy cycle.	Orthographic: Both names share the beginning letter 'N' followed by similar scripted round vowel letters 'a' vs. 'e' in each name and similar scripted ending letter strings '-testo' vs. '-lasta'. Strength: Single strength	Orthographic: The extra letter 'u' in Neulasta provides a longer appearance for the letter string between the upstrokes 'N' and 'l' (vs. the letter string between upstrokes 'N' and 't' in Natesto) and can help differentiate Natesto and Neulasta when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. 6 mg

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
16.	Nitrostat (Nitroglycerin) Tablets 0.3 mg, 0.4 mg, 0.6 mg Usual Dose: Dissolve one tablet under the tongue or in the buccal pouch at the first sign of an acute anginal attack. The dose may be repeated approximately every 5 minutes until relief is obtained. If the pain persists after a total of 3 tablets in a 15 minute period, seek medical attention.	Orthographic: Both names share the beginning letter 'N', a third position upstroke 't', and similar scripted letter strings in similar positions of each name '-esto' vs. '-osta-'.	Orthographic: The extra fourth position letter 'r' and the ending upstroke 't' in Nitrostat provide a different shape and a longer length for this name and can help differentiate Natesto and Nitrostat when scripted. Strength: Single strength vs. multiple strengths (0.3 mg, 0.4 mg, or 0.6 mg) with no overlap between the strengths.
17.	Nutralox (Calcium Carbonate) Chewable Tablets, 420 mg Usual Dose: Chew 2 tablets every three to four hours as symptoms occur. Do not take more than sixteen tablets in 24 hours or more than 2 weeks.	Orthographic: Both names share the beginning letter 'N' followed by similar scripted letters 'a' vs. 'u', a third position upstroke 't', and similar scripted letter strings in the same position of each name '-to' vs. '-lo-'. Strength: Single strength Partial Overlap in the Usual dose: Two (pump actuations vs. tablets)	Orthographic: The extra ending letter 'x' in Nutralox provides a longer appearance for this name and can help differentiate Natesto and Nutralox when scripted. Frequency of Administration: Twice or three times daily vs. every three to four hours.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
18.	Noxafil (Posaconazole) Suspension 40 mg/mL Usual Dose: Prophylaxis of invasive fungal infections: 200 mg (5 mL) orally three times a day. Duration of therapy is based on recovery from neutropenia or immunosuppression. Oropharyngeal Candidiasis: Loading dose of 100 mg (2.5 mL) twice a day on the first day, then 100 mg (2.5 mL) once a day for thirteen days. Oropharyngeal Candidiasis refractory to Itraconazole and/or Fluconazole: 400 mg (10 mL) twice a day.	Orthographic: Both names share the same length (seven letters), beginning letter 'N' followed by similar scripted letter strings '-ate-' vs. '-oxa-' and similar scripted cross strokes in similar positions of each name ('t' in the sixth position vs. 'f' in the fifth position) Strength: Single strength Possible Overlap in the Frequency of Administration: Three times daily. Possible partial Overlap in the Usual Dose: Two (pump actuations vs. teaspoonfuls)	Orthographic: The ending letter string '-to' in Natesto does not appear similar to the ending letter string '-fil' in Noxafil when scripted and can help differentiate Natesto and Noxafil when scripted.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
19.	Nutrifac ZX (Multivitamin and Multimineral) Tablets Usual Dose: One tablet orally once daily.	Orthographic: Both names share the beginning letter 'N' followed by similar scripted letter strings '-at-' vs. '-ut-', and similar scripted letter strings in the same position of each name '-to' vs. '-fa-'. Strength: Single strength	Orthographic: The extra ending letter 'c' in Nutrifac provides a longer appearance for this name and along with the modifier 'ZX', if included, can help differentiate Natesto and Nutrifac ZX when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. one tablet.
20.	Nutri-Tab OB (Prenatal multivitamin and Multimineral) Tablets Usual Dose: One tablet orally once daily.	Orthographic: Both names share the beginning letter 'N' followed by similar scripted letters 'a' vs. 'u', a third position upstroke 't', and similar scripted letter strings in the same position of each name '-to' vs. '-ta-'. Strength: Single strength	Orthographic: The extra ending upstroke letter 'b' in Nutritab provides a different shape and a longer appearance for this name, and along with the modifier 'OB', if included, can help differentiate Natesto and Nutri-Tab OB when scripted. Usual Dose: Two pumps (or 11 mg) vs. one tablet

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
21.	ReFacto (Antihemophilic Factor VIII (recombinant)) Injection 250 units, 500 units, 1000 units, 2000 units Usual Dose: Administer intravenously twice a week for short term routine prophylaxis. The dosage required for hemostasis must be individualized. The calculation of the required dosage of factor VIII is based upon the empirical finding that on average, one international unit of factor VIII per kilogram of body weight raises the plasma factor VIII activity by approximately 2 units/dL per units/kg administered. The required dosage is determined using the following formula: Required units = body weight (kg) × desired factor VIII rise (units/dL or % of normal) × 0.5 (units/kg per units/dL)	Orthographic: Both names share the same shape and length (seven letters), similar scripted beginning letter strings 'Nate-' vs. 'Refa-' when the beginning letters 'N' and 'R' are scripted in lower case, and the same ending letter string '-to'.	Orthographic: The letter string '-es-' in Natesto does not appear similar to the letter string '-ac-' in ReFacto and can help differentiate Natesto and Refacto when scripted. Strength: Single strength vs. multiple strengths (250 units, 500 units, 1000 units, or 2000 units) with no overlap between the product strengths. Usual Dose: Two pumps (or 11 mg) vs. an individualized dosing following a specific formula based on the patient body weight in kilogram and the desired factor VIII rise in units per dL or % of normal.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
22.	Relistor (Methylnaltrexone Bromide) Injection 8 mg/0.4 mL and 12 mg/0.6 mL Usual Dose: The recommended dose is 8 mg subcutaneously every other day, as needed, but no more frequently than one dose in a 24 hour period, for patients weighing 38 kg to less than 62 kg or 12 mg for patients weighing 62 kg to 114 kg. Patients whose weights fall outside of these ranges should be dosed at 0.15 mg/kg.	Orthographic: Both names share similar scripted letters 'Natesto' vs. 'Relisto-' when the beginning letters 'N' and 'R' are scripted in lower case.	Orthographic: The extra ending letter 'r' in Relistor provides a longer appearance for this name and can help differentiate Natesto and Relistor when scripted. Strength: Single strength vs. multiple strengths (8 mg/0.4 mL and 12 mg/0.6 mL) with no overlap between the product strengths. Usual Dose: Two pumps (or 11 mg) vs. 8 mg or 12 mg.
23.	Salactic Film (Salicylic Acid) Topical Solution, 17% Pad, Plaster, or Disc Usual Dose: Apply topically to the affected area(s) for 48 hours to remove corns or calluses.	Orthographic: If the modifier 'Film' is excluded, both names share similar shapes and lengths (seven vs. eight letters), similar scripted beginning letter strings 'Nate-' vs. 'Sala-' and a sixth position upstroke letter 't'. Strength: Single strength	Orthographic: The ending letter string '-ic' in Salactic Film does not appear similar to the ending letter 'o' in Natesto and along with the modifier 'Film', if included with the root name Salactic can help differentiate Natesto and Salactic Film when scripted. Usual Dose: Two pump actuations (or 11 mg) vs. one application.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
24.	Solesta (Dextranomer and Sodium Hyaluronate) Injection Gel 50 mg/15 mg per mL Usual Dose: A total of 4 submucosal injections of 1 mL to be given in the following order: Posterior, left lateral, anterior, and right lateral for fecal incontinence.	Orthographic: Both names share the same shape and length (seven letters), similar scripted beginning letter strings 'Nat-' vs. 'Sol-', identical letter strings '-est-' in the same position of each name, and similar scripted ending round vowel letters 'o' vs. 'a'. Strength: Single strength	Frequency of Administration: Twice or three times daily vs. once Usual Dose: Two pump actuations (or 11 mg) vs. four submucosal injections (or 4 mL) Additionally, Solesta should be administered by qualified health care providers with experience in the treatment of anorectal conditions and who have successfully completed a comprehensive training and certification program in the Solesta injection procedure. Furthermore, this product was approved on May 27, 2011 by the FDA under medical devices.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
25.	Sotret (Isotretinoin) Capsules 10 mg, 20 mg, 30 mg, 40 mg Usual Dose: The recommended dosage range is 0.5 mg/kg/day to 1 mg/kg/day given in two divided doses with food for 15 to 20 weeks.	Orthographic: Both names share similar scripted beginning letter strings 'Na-' vs. 'So-', a third position and a sixth position upstroke 't'. Overlap in the Frequency of Administration: Twice daily	Orthographic: The extra ending letter 'o' in Natesto provides a different shape and a longer appearance for this name and can help differentiate Natesto and Sotret when scripted. Strength: Single strength vs. multiple strengths (10 mg, 20 mg, 30mg, or 40 mg) with no overlap between the product strengths. Usual Dose: Two pump actuations (or 11 mg) vs. weight based dosing with no overlap or achievable dose of 11 mg.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
26.	Sufenta (Sufentanil Citrate) Injection 50 mcg/mL Usual Dose: May be administered intravenously by slow injection or infusion in doses of up to 8 mcg/kg as an analgesic adjunct to general anesthesia, and in doses of greater than 8 mcg/kg as a primary anesthetic agent for induction and maintenance of anesthesia. In children less than 12 years of age: for induction and maintenance of anesthesia an anesthetic dose of 10 mcg/kg to 25 mcg/kg administered with 100% Oxygen.	Orthographic: Both names share the same shape and length (seven letters), similar scripted beginning letter strings 'Nates-' vs. 'Sufen-', a sixth position upstroke 't', and similar scripted ending round vowel letters 'o' vs. 'a'. Strength: Single strength	Usual Dose: Two pump actuations (or 11 mg) vs. 8 mcg/kg, or 10 mcg/kg to 25 mcg/kg with no achievable dose of 11 mg, 22 mg, or 33 mg.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
27.	Sutent (Sunitinib Malate) capsules 12.5 mg, 25 mg, 50 mg Usual Dose: Gastrointestinal stromal tumor: 50 mg orally once daily, 4 weeks on treatment followed by 2 weeks off. Progressive, well-differentiated pancreatic neuroendocrine tumors: 37.5 mg orally once daily, continuously without a scheduled off-treatment period. Dose interruptions and/or dose adjustments of 12.5 mg recommended based on individual safety and tolerability.	Orthographic: Both names share similar scripted beginning letter strings 'Na-' vs. 'Su-', a third position and a sixth position upstroke 't', and similar scripted letter strings in the same position of each name '-es-' vs. '-en-'.	Orthographic: The extra ending letter 'o' in Natesto provides a different shape and longer appearance for this name and can help differentiate Natesto and Sutent when scripted. Strength: Single strength vs. multiple strengths (12.5 mg, 25 mg, or 50 mg) with no overlap between the strengths. Usual Dose: Two pump actuations (or 11 mg) vs. one capsule (or 12.5 mg, 25 mg or 50 mg) with no overlap or achievable dose of 11 mg, 22 mg, or 33 mg.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
28.	Namenda (Memantine Hydrochloride) Tablets, 5 mg, 10 mg Oral Solution, 2 mg/mL Usual Dose: The recommended starting dose is 5 mg orally once daily. The dose should be increased in 5 mg increments to 10 mg/day (5 mg twice daily), 15 mg/day, and 20 mg/day (10 mg twice daily). Patients with severe renal impairment: 5 mg orally twice daily is the target dose.	Orthographic: Both names share the same length (seven letters), beginning letter strings 'Na-', similar scripted letter strings in the same position of each name '-es-' vs. '-en-', a sixth position upstroke 't' vs. 'd', and similar scripted ending round vowel letters 'o' vs. 'a'. Possible Overlap in the Frequency of Administration: Twice daily Possible Partial Overlap in the Usual Dose: Two (pumps vs. tablets, mL's, or teaspoonfuls)	Orthographic: The upstroke 't' in Natesto (vs. the letter 'm' in Namenda) provides a different shape for this name and can help differentiate Natesto and Namenda when scripted.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
29.	Zotex-C (Codeine Phosphate, Phenylephrine Hydrochloride and Pyrilamine maleate) Syrup 10 mg/5 mg/5 mg per 5 mL Usual Dose: Adults and children 12 years of age and older: one to two teaspoonfuls every 4 to 6 hours, not to exceed twelve teaspoonfuls in a 24 hour period. Children 6 to 12 years of age: ½ to 1 teaspoonful every 4 to 6 hours, not to exceed 6 teaspoonfuls in a 24 hour period.	Orthographic: Both names share similar scripted beginning letter strings 'Na-' vs. 'Zo-', a third position upstroke letter 't', and similar scripted letter strings in the same position of each name '-es-' vs. '-ex-'. Additionally, if the hyphen is omitted, and the letter 'c' is attached to the root name Zotex, the letter 'c' may appear similar to the ending letter 'o' in Natesto when scripted. Strength: Single strength Possible Partial Overlap in the Usual Dose: Two (pump actuations vs. teaspoonfuls)	Orthographic: The sixth position upstroke letter 't' in Natesto provides a different shape for this name and can help differentiate Natesto and Zotex-C when scripted.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
30.	Nilandron (Nilutamide) Tablets, 150 mg Usual Dose: 300 mg orally once daily for 30 days, followed thereafter by 150 mg once a day.	Orthographic: Both names share the beginning letter 'N', upstrokes in the third and sixth position of each name 't' vs. 'l' and 't' vs. 'd', similar scripted letter strings in the same position of each name '-es-' vs. '-an-', and the round vowel letter 'o' in similar positions of each name (seventh vs. eighth position). Strength: Single strength Partial Overlap in the Usual Dose: Two (pump actuations vs. tablets)	Orthographic: The extra ending letter 'n' in Nilandron provides a longer appearance for this name and can help differentiate Natesto and Nilandron when scripted.

No.	Natesto (Testosterone) Intranasal Gel 5.5 mg of Testosterone per actuation Usual Dose: Two pump actuations (11 mg of testosterone) intranasally twice daily. (b) (4) [redacted]	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
31.	Lunesta (Eszopiclone) Tablets 1 mg, 2 mg, 3 mg Usual Dose: One tablet orally at bedtime.	Orthographic: Both names consist of seven letters, share similar scripted beginning letter strings 'Na-' vs. 'Lu-', letter string '-est-' in the same position of each name followed by similar scripted ending letters 'o' vs. 'a'. Possible Overlap in the Strength: 11 mg may be misinterpreted as 1 mg or vise versa. Possible Partial Overlap in the Usual Dose: One (pump vs. tab)	Orthographic: The third upstroke letter 't' in Natesto (vs. the letter 'n' in Lunesta) provides a different shape for this name and can help differentiate Natesto and Lunesta when scripted.

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

/s/

MANIZHEH SIAHPOUSHAN
07/11/2013

JAMES H SCHLICK
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CAROL A HOLQUIST
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