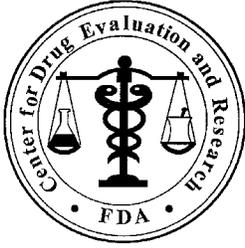


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
200738Orig1s000

PROPRIETARY NAME REVIEW(S)



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

Date: June 4, 2010

To: Wiley Chambers, MD, Acting Director
Division of Anti-Infective and Ophthalmology Products

Through: Denise Toyer, Pharm.D., Deputy Director
Division of Medication Error Prevention and Analysis

From: Kristina A. Toliver, PharmD, Team Leader
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name(s): Lotemax (Loteprednol Etabonate) Ointment, 0.5%

Application Type/Number: NDA 200738

Applicant/Applicant: Bausch & Lomb, Inc

OSE RCM #: 2010-591

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CONTENTS

EXECUTIVE SUMMARY	3
1 BACKGROUND.....	3
1.1 Introduction.....	3
1.2 Product Information	3
2 METHODS AND MATERIALS	3
2.1 Search Criteria	3
2.2 FDA Prescription Analysis Studies.....	4
2.3 Adverse Event Reporting System (AERS) Database.....	4
3 RESULTS.....	5
3.1 Database and Information Sources	5
3.2 Expert Panel Discussion.....	5
3.3 FDA Prescription Analysis Studies.....	5
3.4 FDA Adverse Event Reporting System (AERS) Database.....	6
3.5 Comments from the Division of Anti-Infective and Ophthalmology Products (DAIOP).....	6
3.6 Safety Evaluator Risk Assessment.....	6
4 DISCUSSION	7
4.1 Promotional Review.....	7
4.2 Safety Review	7
5 CONCLUSIONS AND RECOMMENDATIONS	8
5.1 Comments To The Applicant.....	8
6 REFERENCES	9
APPENDICES	11

EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name, Lotemax, Loteprednol Etabonate Ointment, 0.5%. Our evaluation of the proposed proprietary name, Lotemax, did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Lotemax, conditionally acceptable for this product.

However, we recommend at the time of product launch the Applicant inform healthcare practitioners about the introduction of a new dosage form to the Lotemax product line and its intended indication of use.

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

1 BACKGROUND

1.1 INTRODUCTION

This review responds to a request from Bausch and Lomb for an assessment of the proposed proprietary name, Lotemax, for its promotional nature and the potential to contribute to medication errors. NDA # 200738 introduces a new dosage form ophthalmic 'ointment' to the currently marketed Lotemax ophthalmic solution (NDA # 020583) product line. The ointment and the ophthalmic solution will share the same strength, 0.5%, frequency of administration, and indication for treatment post-operative inflammation and pain following ocular surgery. However, the currently marketed Lotemax product is also indicated for steroid-responsive inflammatory conditions of the eye.

The Applicant submitted container labels, carton and insert labeling which will be reviewed under separate cover (OSE Review # 2010-52).

1.2 PRODUCT INFORMATION

Lotemax (Loteprednol Etabonate) Ointment is indicated for the treatment of post-operative inflammation and pain following ocular surgery. The usual dose of Lotemax ointment is to apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period. Lotemax will be supplied in a 3.5 gram tube and should be stored between 15°-25°C (59°-77°F).

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Lotemax.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'L' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{3,4}

³ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

To identify drug names that may look similar to Lotemax, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (two, capital letter ‘L’ and lower case letter ‘t’), down strokes (none), cross strokes (two, lower case letters ‘t’ and ‘x’), and dotted letters (none). Additionally, some letters in Lotemax may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Lotemax.

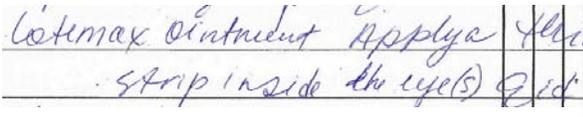
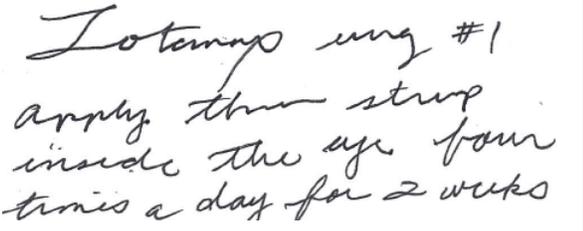
When searching to identify potential names that may sound similar to Lotemax, the DMEPA staff searches for names with similar number of syllables (three), stresses (LO-te-max, lo-TE-max or lo-te-MAX) and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that the spelling and pronunciation of parts of the name can vary (See Appendix B).

The Applicant’s intended pronunciation of the proprietary name is presented as loe' te max. However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

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

Figure 1. Lotemax Study (conducted on April 6, 2010 and May 6, 2010)

HANDWRITTEN PRESCRIPTION ORDERS	VERBAL PRESCRIPTION ORDER
<p><u>Inpatient Prescription Order:</u></p> 	<p>“Lotemax Ointment #1 Apply thin strip inside the eye four times a day”</p>
<p><u>Outpatient Prescription Order:</u></p> 	

2.3 ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE

Since the name Lotemax is currently marketed, DMEPA conducted a search of the Adverse Event Reporting System (AERS) database to identify any name confusion that may be occurring with the currently marketed product. The search was conducted on April 30, 2010 using the active ingredient ‘loteprednol etabonate’, the tradename ‘Lotemax’ and the verbatim term ‘Lotem%’. The MedDRA high level terms (HLT)

⁴ Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

‘Maladministrations’, ‘Medication Errors due to Accidental Exposures’ and Medication Errors NEC’ and the preferred terms ‘Overdose’ and ‘Product Quality Issue’ were used to perform the search.

The reports were manually reviewed to determine if a medication error occurred. Duplicate reports were combined into cases. The cases that described a medication error were categorized by type of error. We reviewed the cases within each category to identify factors that contributed to the medication errors. If a root cause was associated with name confusion of the product, the case was considered pertinent to this review. Those reports that did not describe a medication error or did not describe an error applicable to this review (e.g. errors related to accidental exposures, intentional overdoses, etc.) were excluded from further analysis.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of twenty-one names as having some similarity to the name Lotemax.

Seventeen of the names were thought to look like Lotemax. These include Flomax, Soltamax, Loxitane, Latisse, Lotensin, Lovenox, Fosamax, Topamax, Lotrimin, Lotrisone, Letairis, Beta Care, LoKara, Betimol, Latrix, Lutera, and Vomax. The remaining four names, Lutemax, Lotemax Light, (b)(4), and Lotronex, were thought to look and sound like Lotemax.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of May 19, 2010.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Lotemax.

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

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 43 practitioners responded. Twenty-seven (n=27) practitioners interpreted the name correctly as ‘Lotemax Ointment’. Four (n=4) additional practitioners in the written and verbal studies dropped the dosage form and interpreted the name as ‘Lotemax’. However, Lotemax is not considered as a misinterpretation of the proposed proprietary name since the dosage form is often omitted in the prescription study responses. One of the practitioners who correctly interpreted the name, in the voice study, stated that “*this sounds like and antifungal cream and/or fosamax.*” Fosamax was identified as a look-alike name in Section 3.1

The remaining 12 practitioners, from the inpatient and outpatient written and verbal studies, misinterpreted the drug name. Of these twelve responses, one (n=1) practitioner in the outpatient written study misinterpreted the drug name as ‘Lotemax Cream’ and one (n=1) practitioner in the voice study misinterpreted the drug name as ‘Elaques’. The remaining ten responses were misspellings of the proposed name. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 FDA ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE

A total of 17 cases were retrieved from the AERS search conducted on April 30, 2010. None of the cases were relevant to this review for the following reasons.

- Lotemax was not the suspect drug (n=7)
- Concerns from healthcare practitioners of potential name confusion between a [REDACTED] (b) (4) and the currently marketed product Lanoxin (n=4)
- Wrong drug error where a bottle of Tobramycin was dispensed in a Lotemax carton. The bottle was returned to the manufacturer because it was thought that this was a manufacturing issue. However, the manufacturer indicated that it was impossible for this to occur due to the fact that the Lotemax was manufactured and packaged four months after the Tobramycin lot in question and the Tobramycin bottle is larger than the Lotemax bottle and could not have fit through the packaging line. Further causality could not be determined (n=1)
- Wrong drug error where a practitioner in a physician's office accidentally picked a bottle of Proparacaine Ophthalmic Solution off of the counter and put it in the patient's Lotemax carton instead of the patient's open bottle of Lotemax. There are multiple Proparacaine Ophthalmic Solution on the market and the reporter did not include the manufacturer in the report, therefore it can not be determined if the labels look similar.
- Reporters complaining that the container labels and carton labeling for Lotemax Ophthalmic Solution lack information pertaining to the 'Rx Only' statement (n=1) and lack of a warning statement with regards to use of Lotemax with contact lenses. (n=1)
- Adverse events that were not a result of medication errors (n=2).

3.5 COMMENTS FROM THE DIVISION OF ANTI-INFECTIVE AND OPHTHALMOLOGY PRODUCTS (DAIOP)

3.5.1 Initial Phase of Review

In response to the OSE March 23, 2010 email, the Division of Anti-Infective and Ophthalmology Products (DAIOP) did not have any objections to the proposed proprietary name Lotemax.

3.5.2 Midpoint of Review

DMEPA notified the Division via e-mail that we had no objections to the proposed proprietary name, Lotemax, on May 21, 2010. Per e-mail correspondence from the Division on June 2, 2010, they indicated they had no additional comments regarding the proposed name, Lotemax.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

The Expert Panel identified a total of 21 names as having some similarity to Lotemax. Independent searches by the primary Safety Evaluator did not identify any names that were thought to look-alike or sound-alike Lotemax and represent a potential source of drug name confusion. Thus, a total of 21 names were evaluated for their similarity to the proposed name.

4 DISCUSSION

Lotemax is the proposed proprietary name for Loteprednol Etabonate Ophthalmic Ointment, 0.5%. Lotemax Ophthalmic Ointment will be added to the existing Lotemax product line, which includes Lotemax Ophthalmic Solution. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly.

4.1 PROMOTIONAL REVIEW

DDMAC did not find the name Lotemax promotional. DMEPA and DAIOP concurred with this assessment.

4.2 SAFETY REVIEW

In evaluating the applicant's proposal to expand the existing Lotemax product line to include an ophthalmic ointment, we evaluated the potential risks of confusion within the product line. We also evaluated the potential for confusion between Lotemax Ophthalmic Ointment and currently marketed proprietary and established names.

4.2.1 Lotemax Product Line Extension

When considering the Applicants proposal to use the same proprietary name but differentiate the two products with the dosage forms (i.e., ophthalmic solution vs. ophthalmic ointment), we determined that several currently marketed products utilize a single proprietary name for both their ophthalmic ointment and ophthalmic solution dosage forms. Examples include Ciloxan 0.3%, Gentak 0.3%, and Tobrex 0.3%. There is a possibility for confusion between the two dosage forms resulting in medication errors, because the products share product characteristics including the same strength, frequency of administration, and indication of use (for the treatment of post-operative inflammation and pain following ocular surgery). However, the risk of adverse events from this type of error may be minimal.

Because of the potential risk of confusion between the two dosage forms, we also evaluated the risk of using an alternate proprietary name for the proposed Loteprednol Etabonate ophthalmic ointment dosage form. Loteprednol Etabonate ophthalmic solution is also approved in the use of steroid-responsive inflammatory conditions of the eye while the proposed Loteprenol Etabonate ophthalmic ointment is not. Thus two different practitioners could independently prescribe the currently marketed product for a steroid-responsive inflammatory condition and the proposed ophthalmic ointment (post-operatively) resulting in concomitant administration of two Loteprednol Etabonate products. Concomitant therapy of Loteprednol Etabonate may result in over dosage leading to adverse events.

Thus, DMEPA finds that either naming convention [one proprietary name (Lotemax) or two different proprietary names] carries some risk of confusion and error. However, we concur with the Applicant's proposal to market the proposed Loteprednol Etabonate ophthalmic ointment product under the name, Lotemax, because there appears to be less risk of adverse events than with two different proprietary names that may result in concomitant administration. However, we recommend an educational campaign be conducted to educate practitioners about the introduction of the ophthalmic ointment to the Lotemax product line.

4.2.2 Assessment of Risk Outside the Lotemax Product Line

DMEPA evaluated 21 names for their potential similarity to the proposed proprietary name, Lotemax. Five names were eliminated from further analysis for the following reasons. One name lacked orthographic and/or phonetic similarity to Lotemax; one name was a drug product that is no longer marketed and has no generic equivalents available; one name is an herbal supplement and will not likely have verbal or written orders; one

name is a registered trademark in China; and, the last name is a proprietary name that was found acceptable however, the NDA was approved with a different name (see Appendices D through H).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining 16 names and lead to medication errors. This analysis determined that the name similarity was unlikely to result in medication errors with Lotemax and any of the 16 products for the reasons presented in Appendix I.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Lotemax, is not vulnerable to name confusion that could lead to medication errors nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Lotemax, for this product at this time.

Additionally, we recommend at the time of product launch the Applicant inform healthcare practitioners about the introduction of a new dosage form to the Lotemax product line and its intended indication of use.

Please contact Brantley Dorch, OSE Project Manager, at 301-796-2084, respectively, for questions or clarifications.

5.1 COMMENTS TO THE APPLICANT

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

Additionally, we recommend at the time of product launch you inform healthcare practitioners about the introduction of a new dosage form to the Lotemax product line and its intended indication of use.

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

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

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

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

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

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.⁵

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

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

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.⁶ DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.⁷ DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look

⁵ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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

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

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

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

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

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

throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

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

2. CDER Expert Panel Discussion

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

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

3. FDA Prescription Analysis Studies

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

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

4. Comments from the OND review Division or Generic drugs

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

the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to concur/not concur with DMEPA's final decision.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁸ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

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

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

⁸ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

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

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

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

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

believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. (See Section 4 for limitations of the process).

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Lotemax	Scripted may appear as	Spoken may be interpreted as
L or l	I, S, T, C, V, F or b	
o	a, e, i, u	‘-oh-’, ‘-ow-’
t	b, l	‘-d-’, ‘-duh-’
e	a, i, o, u	‘-uh-’, ‘-ah-’
m	sn, n, rv	‘n’
a	e, i, o, u	
x	c, k	‘-sck’, ‘-s’

Appendix C: FDA Prescription Study Responses

Inpatient Prescription	Outpatient Prescription	Voice Prescription
Lotemax ointment	Lotemax cream	Lotemax (MD called in ointment but available only as an ophthalmic solution)
Lotemax ointment	Lotemax ung	Lotamax ointment
Lotemax ointment	Lotimax ung	Lotemax ointment
Lotemax ointment	Lotamax	Lotamax ointment
Lotemax ointment	Lotrimax ung	Lotomax ointment
Lotemax ointment	Lotemax ?mg?	Elaques ointment
Lotemax Ointment	Lotemax ointment	Lotimax ointment
Lotemax Ointment	Lotanax ointment	Lotemax ointment
Lotemax	Lotemax	Lotemax ung
Lotemax	Lotemax ointment	Lotemax ointment (this sound like an antifungal cream and/or fosamax)
Lotemax ointment	Lotemax ointment	Lotemax ointment
Lotemax ointment	Lotermax ung	Lotemax ointment
Lotemax Ointment	Lotemax ointment	
Lotemax Ointment	Lotemax ung	
Lotimax ointment	Lotemax ointment	
	Lotemax ung (ointment)	

Appendix D: Name Lacking Orthographic and/or Phonetic Similarity

Name	Similarity to Lotemax
Flomax	Look

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

Proprietary Name	Similarity to Lotemax	Status
Soltamox tamoxifen citrate oral solution	Look	NDA 021807* *Orange Book

Appendix F: Product that is an herbal supplement and will not likely have verbal or written orders

Proprietary Name	Similarity to Lotemax	Use
Lutemax lutien	Look and Sound	Lutien deficiency, age related macular degeneration, cataracts, retinitis pigmentosa, diabetes, cardiovascular disease, breast cancer, and colon cancer

Appendix G: Proprietary name that is a registered trademark in a foreign country

Proprietary Name	Similarity to Lotemax	Country Marketed
Lotemax Light	Look and Sound	N/A – Registered in China

Appendix H: Proprietary name that was found unacceptable and NDA approved with a different name

Proprietary Name	Similarity to Lotemax	Use
(b) (4)		

Appendix I: Products with orthographic, phonetic or multiple differentiating product characteristics that minimize the potential for medication errors in the usual practice settings

Product name with potential for confusion	Similarity to Lotemax	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Lotemax (loteprednol etabonate) ointment or solution*		0.5%	<i>Post-Operative Inflammation:</i> Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period <i>*Steroid Responsive Disease Treatment:</i> Apply one to two drops into the conjunctival sac of the affected eye(s) four times a day. During the initial treatment within the first week the dosing may be increased, up to 1 drop every hour, if necessary. *indicated for solution only	
Loxitane* loxapine succinate capsules *Discontinued but generic equivalents are available in the marketplace	Look	5 mg, 10 mg, 20 mg, 50 mg	10 mg to 50 mg orally twice daily	The letters (‘-temax’) in the name Lotemax differentiates it from the letters (‘-xitane’) in the name Loxitane when scripted Dosage form (ophthalmic ointment or ophthalmic solution vs. capsule) Route of administration (ocular vs. oral) Strength (0.5% vs. 5 mg, 10 mg, 20 mg, or 50 mg)

Product name with potential for confusion	Similarity to Lotemax	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Lotemax (loteprednol etabonate) ointment or solution*		0.5%	<p><i>Post-Operative Inflammation:</i> Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period</p> <p><i>*Steroid Responsive Disease Treatment:</i> Apply one to two drops into the conjunctival sac of the affected eye(s) four times a day. During the initial treatment within the first week the dosing may be increased, up to 1 drop every hour, if necessary.</p> <p>*indicated for solution only</p>	
Latisse bimatoprost ophthalmic solution	Look	0.03%	Apply topically to each upper eyelid margin nightly	<p>The name Lotemax appears longer than the name Latisse when scripted</p> <p>The cross stroke of the letter ‘x’ at the end of the name Lotemax differentiates it from name Latisse when scripted</p> <p>Frequency of administration (four times daily vs. once nightly)</p>
Lotensin benzapril hydrochloride tablets	Look	5 mg, 10 mg, 20 mg, 40 mg	20 mg to 80 mg orally administered as a single dose or in two equally divided doses	<p>The cross stroke of the letter ‘x’ at the end of the name Lotemax differentiates it from name Lotensin when scripted</p> <p>Strength (0.05% vs. 5 mg, 10 mg, 20 mg or 40 mg)</p> <p>Dosage form (ophthalmic ointment or ophthalmic solution vs. tablets)</p> <p>Route of administration (ocular vs. oral)</p>

Product name with potential for confusion	Similarity to Lotemax	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Lotemax (loteprednol etabonate) ointment or solution*		0.5%	<i>Post-Operative Inflammation:</i> Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period <i>*Steroid Responsive Disease Treatment:</i> Apply one to two drops into the conjunctival sac of the affected eye(s) four times a day. During the initial treatment within the first week the dosing may be increased, up to 1 drop every hour, if necessary. *indicated for solution only	
Lovenox enoxaparin injection	Look	<i>Prefilled syringes:</i> 30 mg/0.3 mL 40 mg/0.4 mL 60 mg/ 0.6 mL 80 mg/0.8 mL 100 mg/1 mL 120 mg/0.8 mL 150 mg/1 mL <i>Multi-dose vial:</i> 300 mg/3 mL	<i>Subcutaneous:</i> 30 mg twice daily, 40 mg once daily, 1 mg/kg twice daily, or 1.5 mg/kg once daily <i>Intravenous:</i> Single bolus dose of 30 mg	The upstroke of the letter ‘t’ in the name Lotemax differentiates it from the name Lovenox when scripted Strength (0.5% vs. 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, 120 mg, 150 mg or 300 mg/3 mL) Dose (small amount or one to two drops vs. 30 mg, 40 mg, 1 mg/kg or 1.5 mg/kg) Dosage form (ophthalmic ointment or ophthalmic solution vs. injection) Route of administration (ocular vs. subcutaneous or intravenous)
Fosamax alendronate sodium tablets and oral solution	Look	5 mg, 10 mg, 35 mg, 40 mg, 70 mg	35 mg to 70 mg orally once weekly or 5 mg to 40 mg orally once daily	The upstroke of the letter ‘t’ on the name Lotemax differentiates it from the name Fosamax when scripted Strength (0.5% vs. 5 mg, 10 mg, 35 mg, 40 mg, 70 mg) Dosage form (ophthalmic ointment or ophthalmic solution vs. tablet or oral solution) Route of administration (ocular vs. oral)

Product name with potential for confusion	Similarity to Lotemax	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Lotemax (loteprednol etabonate) ointment or solution*		0.5%	<i>Post-Operative Inflammation:</i> Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period <i>*Steroid Responsive Disease Treatment:</i> Apply one to two drops into the conjunctival sac of the affected eye(s) four times a day. During the initial treatment within the first week the dosing may be increased, up to 1 drop every hour, if necessary. *indicated for solution only	
Topamax topiramate tablets and sprinkle capsules	Look	15 mg, 25 mg, 50 mg, 100 mg, 200 mg	25 mg to 400 mg orally in once daily or in two divided doses	The upstroke of the letter ‘t’ on the name Lotemax and the downstroke of the letter ‘p’ in the name Topamax differentiate the two names when scripted Strength (0.5% vs. 15 mg, 25 mg, 50 mg, 100 mg, 200 mg) Dosage form (ointment or ophthalmic solution vs. tablets or sprinkle capsules) Route of administration (ocular vs. oral)
Lotrimin clotrimazole	Look	1 % solution, cream or lotion 10 mg troche lozenge 100 mg and 200 mg vaginal tablet 1% and 2% vaginal cream	Apply a thin layer topically over affected area(s) twice daily Allow one troche to dissolve on the tongue three to five times a day Insert one applicatorful or tablet into the vagina once daily for seven days	The eight letters in the name Lotrimin allow it to look longer than the seven letters in the name Lotemax when scripted Route of administration (ocular vs. topical or vaginal)

Product name with potential for confusion	Similarity to Lotemax	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Lotemax (loteprednol etabonate) ointment or solution*		0.5%	<p><i>Post-Operative Inflammation:</i> Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period</p> <p><i>*Steroid Responsive Disease Treatment:</i> Apply one to two drops into the conjunctival sac of the affected eye(s) four times a day. During the initial treatment within the first week the dosing may be increased, up to 1 drop every hour, if necessary.</p> <p>*indicated for solution only</p>	
Lotrisone Clotrimazole and betamethasone dipropionate cream or lotion	Look	0.05%/1%	Gently massage sufficient Lotrisone cream or lotion into the affected skin areas twice a day, in the morning and evening	The nine letters in the name Lotrisone allow it to look longer than the seven letters in the name Lotemax when scripted Route of administration (ocular vs. topical)
Letairis ambrisentan tablets	Look	5 mg, 10 mg	5 mg to 10 mg once daily	Strength (0.5% vs. 5 mg or 10 mg) Dosage form (ophthalmic ointment or ophthalmic solution vs. tablet) Route of administration (ocular vs. oral)
Beta Care purified water and propylene glycol cream and lotion (moisturizer and skin cleanser)	Look	N/A	<p><i>Skin cleanser:</i> Apply on a clean towel and apply topically. Rinse and pat dry</p> <p><i>Moisturizer:</i> Apply topically two to three times a day</p>	The ending letters (‘-max’ vs. ‘-care’) in the name Lotemax and the name Betacare differentiate the two names when scripted Route of administration (ocular vs. topical)

Product name with potential for confusion	Similarity to Lotemax	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Lotemax (loteprednol etabonate) ointment or solution*		0.5%	<p><i>Post-Operative Inflammation:</i> Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period</p> <p><i>*Steroid Responsive Disease Treatment:</i> Apply one to two drops into the conjunctival sac of the affected eye(s) four times a day. During the initial treatment within the first week the dosing may be increased, up to 1 drop every hour, if necessary.</p> <p>*indicated for solution only</p>	
LoKara desonide lotion	Look	0.05%	Apply topically two to three times a day sparingly	<p>The seven letters and the ending letter ‘-x’ in the name Lotemax allows it to look longer than the six letters in the name LoKara which differentiates the names when scripted</p> <p>Route of administration (ocular vs. topical)</p>
Betimol Timolol ophthalmic solution	Look	0.25%, 0.5%	The usual starting dose is one drop of 0.25% in affected eye(s) twice a day. If the clinical response is not adequate, the dosage may be changed to one drop of 0.5% solution in the affected eye(s) twice a day	The ending letter ‘-x’ in the name Lotemax differentiates it from the upstroke of the letter ‘-l’ at the end of the name Betimol
Latrix urea emulsion	Look	45%	Apply to affected skin twice per day, or damaged nails twice per day	<p>The seven letters and the letter ‘-e-’ in the middle of the name Lotemax allow it to look longer the six letters in the name Latrix</p> <p>Route of administration (ocular vs. topical)</p>

Product name with potential for confusion	Similarity to Lotemax	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Lotemax (loteprednol etabonate) ointment or solution*		0.5%	<i>Post-Operative Inflammation:</i> Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period <i>*Steroid Responsive Disease Treatment:</i> Apply one to two drops into the conjunctival sac of the affected eye(s) four times a day. During the initial treatment within the first week the dosing may be increased, up to 1 drop every hour, if necessary. *indicated for solution only	
Lutera ethinyl estradiol and levonorgestrel	Look	20 mcg/1 mg	One tablet orally once daily	The ending letter ‘-x’ in the name Lotemax differentiates it from the name Lutera when scripted Dosage form (ophthalmic ointment or ophthalmic solution vs. tablet) Route of administration (ocular vs. oral)
Volmax* albuterol sulfate extended release tablets *Discontinued but generic equivalents are available in the marketplace	Look	4 mg, 8 mg	8 mg orally every 12 hours	The middle letter ‘-e-’ in the name Lotemax differentiates it from the name Volmax when scripted Strength (0.5% vs. 4 mg or 8 mg) Dosage form (ophthalmic ointment or ophthalmic solution vs. extended release tablet) Route of administration (ocular vs. oral)

Product name with potential for confusion	Similarity to Lotemax	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Lotemax (loteprednol etabonate) ointment or solution*		0.5%	<i>Post-Operative Inflammation:</i> Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the post-operative period <i>*Steroid Responsive Disease Treatment:</i> Apply one to two drops into the conjunctival sac of the affected eye(s) four times a day. During the initial treatment within the first week the dosing may be increased, up to 1 drop every hour, if necessary. *indicated for solution only	
Lotronex alose tron hydrochloride tablets	Look and Sound	0.5 mg, 1 mg	Starting dose is 0.5 mg orally twice a day. May increase dose to 1 mg orally twice a day after 4 weeks	The letter ‘-r-’ in the name Lotronex differentiates it from the name Lotemax when spoken and scripted The short ă sound at the end of the name Lotemăx differentiates it from the short ě sound at the end of the name Lotroněx Dosage form (ophthalmic ointment or ophthalmic solution vs. tablet) Route of administration (ocular vs. oral)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200738	ORIG-1	BAUSCH AND LOMB INC	LOTEPREDNOL ETABONATE OINTMENT, 0.5%

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

/s/

KRISTINA C ARNWINE
06/04/2010

DENISE P TOYER
06/04/2010