

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
202236Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: April 2, 2011

Reviewer: Yelena Maslov, Pharm.D., Acting team Leader
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Dymista (Azelastine Hydrochloride and Fluticasone Propionate)
Nasal Spray, 137 mcg/50 mcg per actuation

Application Type/Number: NDA 202236

Applicant/sponsor: Meda Pharmaceuticals

OSE RCM #: 2011-3906

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Dymista, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Dymista, acceptable in OSE Review #2011-1448 dated July 14, 2011.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2011-1448. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded one new name [REDACTED]^{(b) (4)} thought to look similar to Dymista and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with [REDACTED]^{(b) (4)} and lead to medication errors. This analysis determined that the name similarity between Dymista and the identified names was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of April 2, 2011. OPDP re-reviewed the proposed name on November 3, 2011, and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Dymista, did not identify any vulnerabilities that would result in medication errors with any additional name(s) noted in this review. Thus, DMEPA has no objection to the proprietary name, Dymista, for this product at this time.

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

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

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4 REFERENCES

1. Maslov, Yelena. **Proprietary Name Review for Dymista. OSE Review #2011-1488**
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
4. **Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request**
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: Failure Mode and Effect Analysis Table

<p>Proposed name: Dymista (Azelaatine Hydrochloride and Fluticasone Propionate) Nasal Spray</p>	<p>Strength(s): 137 mcg/50 mcg per actuation</p>	<p>Usual dose: One spray into each nostril twice daily</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>

(b) (4)



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/s/

YELENA L MASLOV
04/02/2012

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

Proprietary Name Review

Date: July 13, 2011

Reviewer: Yelena Maslov, Pharm.D., Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader: Zachary Oleszczuk, Pharm.D., Team Leader
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, R.Ph., Director
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Dymista (Azelastine Hydrochloride and Fluticasone Propionate)
Nasal Spray, 137 mcg/50 mcg per actuation

Application Type/Number: NDA 202236

Applicant/sponsor: Meda Pharmaceuticals

OSE RCM #: 2011-1448

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Dymista, for April 29, 2011 submission of the New Drug Application (NDA 202236). DMEPA found the proposed name, Dymista, acceptable in the IND 077363 in OSE Review #2010-2403, dated April 15, 2011. Since the IND review was completed only three months ago, DMEPA completed an abbreviated name review.

2 METHODS AND DISCUSSION

2.1 PROMOTIONAL ASSESSMENT

DDMAC re-evaluated the proposed proprietary name, Dymista, on May 19, 2011, and found it acceptable from the promotional perspective. DMEPA and the Division of Pulmonary, Allergy and Rheumatology Products (DPARP) concur with DDMAC's assessment.

2.2 SAFETY ASSESSMENT

DMEPA searched a standard set of databases and information sources (see Section 4) to identify names with orthographic and phonetic similarity to the proposed name since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2010-2403. Since none of the proposed product characteristics were altered, we did not re-evaluate previous names of concern. The searches of the databases yielded eight new names (Ayr Saline Mist, Glyoxide, Oxyfast, Duohist DH, Dyna-hex, Dynapen, Symlin, and Gymiso), thought to look or sound similar to Dymista and represent a potential source of drug name confusion.

DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with any of the eight names and lead to medication errors. This analysis determined that the name similarity between Dymista and the identified names was unlikely to result in medication error for the reasons presented in Appendices A and B.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 14, 2011.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Dymista, did not identify any vulnerabilities that would result in medication errors with the additional name noted in this review. Thus, DMEPA has no objection to the proprietary name, Dymista, for this product at this time. However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

Additionally, the name, Dymista, must be re-reviewed 90 days prior to the NDA approval.

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

4. REFERENCES

1. *Crandall, Anne. OSE Review #2010-2403, Dymista Proprietary Name Review, April 15, 2011.*

2. *Micromedex Integrated Index (<http://csi.micromedex.com>)*

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

3. *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.

4. *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.

5. *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.

6. *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.

7. *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.

8. *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.

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

USPTO provides information regarding patent and trademarks.

10. 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.

11. 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.

12. 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.

13. Access Medicine Database (<http://www.accessmedicine.com/drugs.aspx>)

Access Medicine contains full-text information from approximately 60 medical titles: it includes tables and references. Among the database titles are: Goodman and Gilman's The Pharmacological Basis of Therapeutics, Current Medical Diagnosis and Treatment, Tintinalli's Emergency Medicine, and Hurst's the Heart.

14. 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.

15. Red Book Pharmacy's Fundamental Reference

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

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

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

17. Medical Abbreviations Book

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

18. LabelDataPlus Database (<http://www.labeldataplus.com/index.php?ns=1>)

LabelDataPlus database covers a total of 36773 drug labels. This includes Human prescription drug labels as well as Active Pharmaceutical Ingredients (APIs), OTC (Application and Monograph) drugs, Homeopathic drugs, Unapproved drugs, and Veterinary drugs.

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

Product Name	Similarity to Edurant	Failure preventions
Ayr Saline Mist (Sodium Chloride)	Looks alike	Lacks sufficient orthographic similarity
Duohist DH (Chlorpheniramine, Dihydrocodeine, Phenylephrine)	Looks alike	The product is discontinued without generic equivalent
Gymiso (Misoprostol)	Looks alike and sounds alike	Foreign product available in France

Appendix B: Failure Mode and Effect Analysis Table

Proposed name: Dymista (Azelastine Hydrochloride and Fluticasone Propionate) Nasal Spray	Strength(s): 137 mcg/50 mcg per actuation	Usual dose: One spray into each nostril twice daily
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
Gly-oxide (Carbamide Peroxide) Dental Gel, 10% Dental Solution, 10% <u>Usual Dose</u> Apply several drops (solution) or apply a thin layer (gel) to affected area of the mouth four times per day after meals and at bedtime.	<u>Orthographic</u> Both names share the letter 'y'. Additionally, the letters 'D' and 't' in Dymista may appear similar to the letters 'G' and 'd' in Gly-oxide when scripted. <u>Strength</u> Both products are available in a single strength; thus, the strength may be omitted	<u>Orthographic</u> The name Dymista contains 2 upstrokes vs. the name Gly-oxide contains 3 upstrokes. Additionally, the letter string 'mis' in Dymista lacks orthographic similarity to the letter string 'oxi' in Gly-oxide when scripted. <u>Dosage form</u> Nasal spray vs. solution or gel <u>Usual Dose</u> One spar to each nostril vs. Apply several drops (solution) or apply a thin layer (gel) <u>Frequency of Administration</u> Twice daily vs. five times daily (four times per day after meals and at bedtime).

<p>Oxyfast (Oxycodone) Oral Solution, 600 mg/30 mL (20 mg/mL)</p> <p><u>Usual Dose</u> 15 mg to 20 mg orally every 6 hours as needed for pain</p>	<p><u>Orthographic</u> Both names share the letter 'y' and the letter string 'st'. Additionally, the letter 'D' may appear similar to the letter 'O' when scripted.</p> <p><u>Strength</u> Both products are available in a single strength; thus, the strength may be omitted for pain</p>	<p><u>Orthographic</u> The name Dymista contains 1 down stroke vs. the name Oxyfast contains 2 down strokes. Additionally, the letter string 'mi' in Dymista lacks orthographic similarity to the letter string 'fa' in Oxyfast when scripted. Also, although both names share the letter 'y' and the letter string 'st', the letters are located in different positions of the names.</p> <p><u>Usual Dose</u> One spray to each nostril vs. 15 mg to 20 mg</p> <p><u>Frequency of Administration</u> Twice daily vs. every 6 hours as needed.</p>
<p>Dyna-hex (Chlorhexidine Gluconate) Topical Solution, 4%</p> <p><u>Usual Dose</u> Surgical Scrub: apply 5 mL and scrub for 3 minutes using a wet brush. Pre-operative patient preparation: apply liberally to surgical site and swab for 2 minutes or more.</p>	<p><u>Orthographic</u> Both names share the letter string 'Dy-'. Additionally, the letter string 'mi' and the letter 't' in Dymista may appear similar to the letter string 'na' and the letter 'h' in Dyna-hex when scripted.</p> <p><u>Strength</u> Both products are available in a single strength; thus, the strength may be omitted</p>	<p><u>Usual Dose</u> One spray to each nostril vs. apply 5 mL and scrub for 3 minutes or apply liberally to surgical site and swab for 2 minutes or more</p> <p><u>Frequency of Administration</u> Twice daily vs. once</p>

<p>Dynapen* (Dicloxacillin) Capsules, 250 mg and 500 mg Although the proprietary name is discontinued, multiple generic products are still on the market.</p> <p><u>Usual Dose</u> 250 mg to 500 mg orally every 6 hours.</p>	<p><u>Orthographic</u> Both names share the letter string ‘Dy-’. Additionally, the letter string ‘mi’ and the letter ‘a’ in Dymista may appear similar to the letter string ‘na’ in Dynapen and the letter ‘n’ when scripted.</p>	<p><u>Orthographic</u> The name Dymista contains 1 down stroke and 2 upstrokes vs. the name Dynapen contains 2 down strokes and 1 upstroke. Additionally, the letter string ‘st’ in Dymista lacks orthographic similarity to the letter string ‘pe’ in Dynapen when scripted.</p> <p><u>Strength</u> Although Dymista can be dosed at 50 mcg of Fluticasone Propionate and Dynapen at 500 mg, the confusion is unlikely because Dymista also contains Azelastine Hydrochloride as the active ingredient in the product and the strength of the first ingredient is rarely omitted.</p> <p><u>Frequency of Administration</u> Twice daily vs. every 6 hours.</p>
<p>Symlin (Pramlintide Acetate) Injection, 0.6 mg/mL and 1 mg/mL</p> <p><u>Usual Dose</u> 15 mcg to 60 mcg subcutaneously prior to each meal</p>	<p><u>Orthographic</u> Both names contain 1 down stroke and 2 upstrokes. Additionally, the letter string ‘Dym’ and the letter ‘a’ may appear similar to the letter string ‘Sym’ and the letter ‘n’ when scripted.</p>	<p><u>Orthographic</u> The name Dymista appears longer than the name Symlin, because it contains more letters (7 letters vs. 6 letters) and the extra letter is the wider letter ‘s’. Additionally, the upstroke ‘t’ in Dymista is in different position than the upstroke ‘l’ in Symlin.</p> <p><u>Strength</u> Single strength (137 mcg/50 mcg per actuation) vs. 0.6 mg/mL and 1 mg/mL</p> <p><u>Route of Administration</u> Nasal vs. subcutaneous.</p> <p><u>Usual Dose</u> One spray to each nostril vs. 15 mcg to 60 mcg subcutaneously</p>

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