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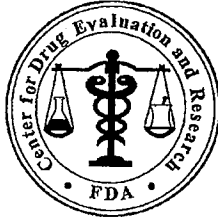
APPLICATION NUMBER:
22-387

<u>PROPRIETARY NAME REVIEW(S)</u>

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 29, 2009
To:	Norman Stockbridge, MD Director, Division of Cardiovascular and Renal Products
Through:	Carlos Mena-Grillasca, RPh, Acting Team Leader Denise Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis
From:	Judy Park, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Final Proprietary Name Review
Drug Name(s):	Tyvaso (Treprostinil) Inhalation Solution 0.6 mg/mL
Application Type/Number:	NDA 22-387
Applicant:	United Therapeutics Corporation
OSE RCM #:	2009-814

Note: This review contains proprietary and confidential information that should not be released to the public.

CONTENTS

EXECUTIVE SUMMARY

This re-assessment of this proprietary name is written in response to a notification that treprostinil will be approved within 90 days. DMEPA found the proposed proprietary name, Tyvaso, acceptable in OSE Review #2008-1113 on February 19, 2009. Since that review, none of Tyvaso's product characteristics have changed.

During this re-review we identified 9 new names for their similarity to Tyvaso. The results of the Failure Mode Effects Analysis found that the proposed name, Tyvaso, is not vulnerable to name confusion that could lead to medication errors with any of 9 names. Thus, the Division of Medication Error Prevention and Analysis does not object to the use of the proprietary name, Tyvaso, for this product.

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 Tyvaso should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

1   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 re-assessment of a proprietary name 90 days prior to approval of an application. Section 1.1 identifies the specific search criteria associated with the proposed proprietary name, Tyvaso.

1.1   PROPRIETARY NAME RISK ASSESSMENT

For this review, particular consideration was given to drug names beginning with the letter 'T' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to Tyvaso, DMEPA also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), upstrokes (one, capital letter 'T'), downstokes (lower case 'y'), cross-strokes (none), and dotted letters (none). Additionally, several letters in Tyvaso may be vulnerable to ambiguity when scripted, including the letter 'T' may appear as 'F,' 'L,' 'S,' 'Z,' or 'A'; lower case 'y' may appear as a lower case 'g' or 'p'; lower case 'v' may appear as 'c,' 'r,' 's,' or 'z'; and 'a' and 'o' may appear as 'a,' 'e,' 'i,' 'o,' or 'u'. As such, the staff also considers these alternate appearances when identifying drug names that may look similar to Tyvaso.

When searching to identify potential names that may sound similar to Tyvaso, the DMEPA staff searches for names with similar number of syllables (three), stresses (ty-VA-so or TY-va-so), and placement of vowel and consonant sounds. Additionally, several letters in Tyvaso may be

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

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

vulnerable to misinterpretation when spoken, including 'Ty' may be interpreted as 'Zy'; 'v' may be interpreted as 'b' and 's' may be interpreted as 'c' or 'z'. As such, the staff also considers these alternate pronunciations when identifying drug names that may sound similar to Tyvaso. The Applicant's intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

2 RESULTS

2.1 DATABASE AND INFORMATION SOURCES

The searches of the databases listed in Section 6 yielded a total of 19 names as having some similarity to the name Tyvaso.

Seventeen of the 19 names were thought to look like Tyvaso, which include: Lyrica, Lysine, ——— Tazorac, Tequin, ——— Tyrazol, Tyrex, Tyrex-2, ——— Tysabri, Tyverb, Tyzeka, Tyzine, Vyvanse, Zyrona, and Zyvox. One additional name, Tri-Vi-Sol, was thought to sound similar to Tyvaso. One name, Travasol, was thought to look and sound similar to Tyvaso.   b(4)

A search of the United States Adopted Names (USAN) stem list on June 22, 2009 identified no USAN stems contained in the proposed name, Tyvaso.

2.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by the DMEPA staff (see section 2.1 above), and noted no additional names thought to have orthographic or phonetic similarity to Tyvaso.

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

2.3 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator did not identify any additional names thought to look similar to Tyvaso and represent a potential source of drug name confusion.

Ten of the 19 names were identified in the previous Tyvaso proprietary name review (See Appendix B). None of Tyvaso's product characteristics have changed since the previous review. Therefore, the original assessment is maintained. Please see OSE #2008-1113 for a detailed analysis of these names.

3 DISCUSSION

Nine names were evaluated for their potential similarity to the proposed name, Tyvaso. Four names lacked orthographic and/or phonetic similarity to Tyvaso and were not evaluated further (See Appendix C).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed name could potentially be confused with the remaining 5 names and lead to medication errors. This analysis determined that the name similarity between Tyvaso was unlikely to result in medication errors with any of the 5 products for the reasons presented in Appendices D and E.

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