CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-030

PROPRIETARY NAME REVIEW(S)

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

Date:	October 15, 2008
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Subject:	Final Proprietary Name, Label, and Labeling Review
Drug Name(s):	Toviaz (Fesoterodine Fumarate) Extended-release Tablets
Application Type/Number:	NDA # 22-030
Applicant/Applicant:	Pfizer, Inc. (Schwarz Pharma)
OSE RCM #:	2008-810

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

CONTENTS

EXECUTIVE SUMMARY

Toviaz, has some similarity to other proprietary and established drug names, but the findings of the Failure Modes and Effects Analysis (FMEA) indicates that the proposed name is not vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objections to the use of the proprietary name, Toviaz for this product.

However; if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. Additionally, if the product approval is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

The results of the Label and Labeling Risk Assessment find the proposed container labels and labeling introduce vulnerabilities that could lead to medication errors. DMEPA's recommendations for label and labeling modifications are found in Section 5.2.

1 BACKGROUND

1.1 INTRODUCTION

This review was written in response to a request from the Division of Reproductive and Urologic Products (DRUP) to re-evaluate the product for its potential to contribute to medication errors. The proposed proprietary name, Toviaz, is evaluated to determine if the name could be potentially confused with other proprietary or established drug names. The container label, carton and insert labeling were submitted to DMEPA at the time of this review.

1.2 REGULATORY HISTORY

DMEPA reviewed the proposed name, Toviaz, previously with no objections to the name in OSE Review 2007-2078 (dated April 22, 2008). However, the container labels, carton and insert labeling were not submitted to DMEPA at the time of that review.

1.3 PRODUCT INFORMATION

Toviaz is the proposed name for Fesoterodine Fumarate Extended-release tablets. Fesoterodine fumarate is a competitive muscarinic receptor antagonist in an extended-release tablet formulation. Toviaz is proposed to be indicated for the treatment of overactive bladder with symptoms of urinary urgency, frequency, and/or urge incontinence.

The recommended starting dose is 4 mg once daily. Based upon individual response and tolerability, the dose may be increased to 8 mg once daily.

2 METHODS AND MATERIALS

This section describes the methods and materials used by the DMEPA staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment). The primary focus of the assessment is to identify and remedy potential sources of medication error prior to drug approval. 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]

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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.

2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Toviaz, and the proprietary and established names of drug products existing in the marketplace and those pending IND, BLA, NDA, and ANDA products currently under review by CDER.

For the proprietary name, Toviaz, the medication error staff of DMEPA search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2).

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 (see detail 2.1.4). The overall risk assessment is based on the findings of a Failure Modes and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.[2] FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in 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. As such, the Staff consider the product characteristics associated with the proposed drug throughout the risk assessment, since 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 drug name include, but are not limited to established name of the proposed product, the proposed indication, 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 considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[3]

2.1.1 Search Criteria

The medication error staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

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.[4][5]

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

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

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

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

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