CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-926

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:	April 14, 2008
To:	Russell Katz, MD, Director Division of Neurology Products, HFD-120
Thru:	Linda Y. Kim-Jung, PharmD, Team Leader Denise P. Toyer, PharmD, Deputy Director Carol A. Holquist, R.Ph., Director Division of Medication Error Prevention, HFD-420
From:	Loretta Holmes, BSN, PharmD, Safety Evaluator Division of Medication Error Prevention, HFD-420
Subject:	Proprietary Name, Label, and Labeling Review
Drug Name:	Treximet (Sumatriptan and Naproxen Sodium) Tablets 85 mg/500 mg
Application Type/Number:	NDA 21-926
Applicant:	Pozen, Inc.
OSE RCM #:	2008-433

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

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EXECUTIVE SUMMARY

The results of the Proprietary Name Risk Assessment found that the proposed name,Treximet, has some similarity to other proprietary and established drug names, but the findings of the FMEA indicate that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention has no objections to the use of the proprietary name, Treximet, for this product.

The results of the Label and Labeling Risk Assessment found that the presentation of the statement of strength on the container labels and carton labeling and omission of the drug administration precaution on the carton labeling render the labels and labeling vulnerable to confusion that could lead to medication errors. The Division of Medication Error Prevention and Analysis believes the risks we have identified can be addressed and mitigated prior to drug approval and provide recommendations in Section 6.

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

1 BACKGROUND

1.1 INTRODUCTION

This review was written in response to a request from the Division of Neurology Products (HFD-120) for re-assessment of the proposed proprietary name, Treximet, regarding potential name confusion with other proprietary or established drug names.

1.2 REGULATORY HISTORY

The Division of Medication Error Prevention previously reviewed the names [redacted] (primary) and Treximet (secondary) for this NDA (see OSE Review 2007-1571, dated August 16, 2007) and had no objections to the use of those names at that time. The Applicant has chosen the secondary name, Treximet, for their product.

1.3 PRODUCT INFORMATION

Treximet contains sumatriptan (as the succinate), a selective 5-hydroxytryptamine$_1$ (5-HT$_1$) receptor subtype agonist, and naproxen sodium, a member of the arylacetic acid group of nonsteroidal anti-inflammatory drugs. Treximet is indicated for the acute treatment of migraine attacks with or without aura in adults. Treximet will be available as 85 mg/500 mg tablets. The recommended dose is one tablet with a maximum dose of two tablets in 24 hours. Dosing of tablets should be at least two hours apart. Treximet may be administered with or without food. Tablets should not be split, crushed, or chewed. Treximet has a boxed warning in the package insert labeling concerning cardiovascular and gastrointestinal risks. The product will be supplied in compact containers of 9 tablets with a specially formulated, non-removable dessicant.

2 METHODS AND MATERIALS

This section consists of two sections which describe the methods and materials used by the Division of Medication Error Prevention Medication Error Staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment). The primary focus for both of the assessments is to identify and remedy potential sources of medication error prior to drug approval. The Division of Medication Error Prevention 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]

2.1 PROPRIETARY NAME RISK ASSESSMENT

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

For the proprietary name,Treximet, the Medication Error Staff of the Division of Medication Error Prevention 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 a CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). The Division of Medication Error Prevention normally conducts internal CDER prescription analysis studies and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment. However, since this name was previously evaluated, CDER prescription analysis studies were not conducted upon re-review of Treximet.

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 2.1.3). 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. The Division of Medication Error Prevention 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 considers 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, the Division of Medication Error Prevention 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]

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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] 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.

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