CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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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:	May 13, 2008
To:	Russell Katz, MD, Director Division of Neurology Products Bob Rappaport, MD, Director Division of Anesthesia, Analgesia and Rheumatology Products
Thru:	Kellie Taylor, PharmD, MPH, Team Leader Denise Toyer, PharmD, Deputy Director Division of Medication Errors and Technical Support
From:	Judy Park, PharmD, Safety Evaluator Division of Medication Errors and Technical Support
Subject:	Proprietary Name, Label, and Labeling Review for Vimpat
Drug Name(s):	Vimpat (Lacosamide) Tablets, Oral Syrup, and Injection
Application Type/Number:	NDA 22-253, NDA 22-254, NDA 22-255, (b) (4)
Applicant:	Schwarz Biosciences, Inc.
OSE RCM #:	2007-1610

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EXECUTIVE SUMMARY

The Proprietary Name Risk Assessment found that the proposed name, Vimpat, has some similarity to other proprietary and established drug names, but the Failure Modes and Effects Analysis (FMEA) findings indicate that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors. This finding was consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant. Thus, the Division of Medication Error Prevention does not object to the use of the proprietary name, Vimpat, for this product.

The results of the Label and Labeling Risk Assessment found that the presentation of information and design of the proposed insert labeling and measuring devices appear to be vulnerable to confusion that could lead to medication errors. We believe the risks we have identified can be addressed and mitigated prior to drug approval, and provides recommendations in Section 5.2 that aim at reducing the risk of medication errors.

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

1 BACKGROUND

1.1 INTRODUCTION

This consult was written in response to a request from the Division of Neurology to evaluate the proprietary name, insert labeling, and measuring device of Vimpat for its potential to contribute to medication errors. The proposed proprietary name, Vimpat, was evaluated to determine if the name could be potentially confused with other proprietary or established drug names. A forthcoming review (OSE Review #2008-633) will assess the container labels and carton labeling.

1.2 PRODUCT INFORMATION

Vimpat (Lacosamide) is a new molecular entity indicated for partial-onset seizures as adjunctive therapy in patients aged (b) (4) years and older. (b) (4) The recommended dose for partial onset seizures is 100 mg per day twice daily initially, then increased to 200 mg per day to 400 mg per day. (b) (4) The dose can be increased at weekly intervals by increments of 100 mg per day based on clinical response and tolerability. The maximum daily dosage of Vimpat is (b) (4) per day. When switching from oral to intravenous dose, the initial total daily intravenous dosage should equal the oral total daily dosage and frequency. The parenteral formulation of Vimpat can be administered without further dilution or may be mixed in a compatible diluent and should be administered intravenously over (b) (4). Vimpat will be available in 50 mg, 100 mg, 150 mg, 200 mg (b) (4) oral syrup, and 10 mg/mL solution for injection. (b) (4). For partial seizure indication, tablets, oral syrup and injectables are indicated.

2 METHODS AND MATERIALS

This section consists of two sections which describe the methods and materials used by the Division of Medication Error Prevention staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment) and labeling, and/or packaging risk assessment (see 2.2 Insert Label 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, Vimpat, 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, Vimpat, the Division of Medication Error Prevention staff 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). We also conduct internal CDER prescription analysis studies (see 2.1.2), and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment (see detail 2.1.4).

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. We use the clinical expertise of the Medication Error Prevention 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, we consider 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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