CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-192

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:	February 11, 2009
To:	Thomas Laughren, MD, Director Division of Psychiatry Products
Through:	Todd Bridges, RPh, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Diane C. Smith, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Fanapt (Iloperidone) Tablets 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg
Application Type/Number:	NDA # 22-192
Applicant:	Vanda Pharmaceuticals
OSE RCM #:	2009-69

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EXECUTIVE SUMMARY

The Proprietary Name Risk Assessment findings indicate that the proposed name, Fanapt, is not vulnerable to name confusion that could lead to medication errors. As such, we have no objections to the use of the proprietary name, Fanapt, for this product. The Division of Psychiatry Products concurs with this assessment.

However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this Risk Assessment finding, and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment and, as such, the conclusions on re-review of the name are subject to change. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from the Division of Psychiatry Products for assessment of the proprietary name, Fanapt, regarding potential name confusion with other proprietary or established drug names. Labels and labeling will be evaluated in a separate forthcoming review (OSE review # 2009-70). Additionally, the Applicant submitted an independent analysis of the name by [redacted] subsidiary of [redacted] for review and comment. b(4)

1.2 REGULATORY HISTORY

The Division of Medication Error Prevention and Analysis objected to the primary proposed proprietary name Fiapta in OSE Review 2007-537, dated April 14, 2008, because of orthographic similarity and overlapping product characteristics to Lipitor. Subsequently, DMEPA reviewed the Applicant's secondary name, Fanapta, in OSE Review 2007-538 dated June 3, 2008. DMEPA objected to the name Fanapta because the name had orthographic similarities and overlapping product characteristics with Lunesta. Thus, in a letter dated June 6, 2008, the Applicant was asked to submit two alternate proprietary names for review. As a result, Vanda Pharmaceuticals submitted a request for proposed proprietary name review of the proprietary name, Fanapt, on November 19, 2008.

1.3 PRODUCT INFORMATION

Fanapt (Iloperidone) is an atypical antipsychotic agent indicated for the acute treatment of schizophrenia in adults. The recommended dose is 12 mg to 24 mg per day administered twice daily (BID) based on clinical response. This target dose range should be achieved through the following daily dosage adjustments until the desired maintenance dose is achieved: 1 mg BID, 2 mg BID, 4 mg BID, 6 mg BID, 8 mg BID, 10 mg BID and 12 mg BID on days 1, 2, 3, 4, 5, 6 and 7, respectively.

Fanapt will be supplied as follows:

	Professional Sample Bottle of 14 tablets	Trade Container of 60 tablets	Professional Blister Cards
Tablet Strength			
1 mg		X	X
2 mg		X	X
4 mg	X	X	X
6 mg	X	X	X
8 mg	X	X	X
10 mg	X	X	X
12 mg	X	X	X

2 METHODS AND MATERIALS

This section consists of 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 for all of the assessments is to identify and remedy potential sources of medication error prior to drug approval. Our Division 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, Fanapt, 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, Fanapt, the DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see section 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 section 2.1.3). The Division of Medication Error Prevention and Analysis also conducts internal FDA prescription analysis studies (see 2.1.2), and, when provided, external prescription analysis studies (see 2.1.5) results are considered and incorporated into the overall risk assessment.

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 2.4). The overall risk assessment is based on the findings of a Failure Mode 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

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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.

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