

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-173**

**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: August 4, 2009

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Subject: Proprietary Name Review

Drug Name(s): Zyprexa Relprevv (Olanzapine for Extended-release Injectable Suspension)

Application Type/Number: NDA 22-173

Applicant: Eli Lilly and Company

OSE RCM #: 2009-467

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## **1 INTRODUCTION**

This review is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Zyprexa Relprevv, acceptable in OSE Review #2008-1774, dated December 24, 2008. Since that review, none of Zyprexa Relprevv's product characteristics have been altered. Additionally, on March 26, 2009, DDMAC reviewed the proposed name and had no concerns regarding the proposed name from a promotional perspective and did not offer any additional comments relating to the proposed name. Furthermore, the review Division did not have any concerns with the proposed name, Zyprexa Relprevv during our initial review.

## **2 METHODS AND RESULTS**

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors. We used the same search criteria used in OSE Review #2008-1774 for the proposed proprietary name, Zyprexa Relprevv.

The searches of the databases did not yield any new names thought to look or sound similar to Zyprexa Relprevv and represent a potential source of drug name confusion.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of July 29, 2009.

## **3 CONCLUSIONS AND RECOMMENDATIONS**

The re-review of Zyprexa Relprevv did not identify any additional names thought to look or sound similar to the proposed name since our last review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Zyprexa Relprevv, for this product at this time.

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

#### 4 REFERENCES

1. OSE review # 2008-1774 Proprietary Name Review of Zyprexa Relprevv; Hamilton-Stokes, Deveonne

2. *Drugs@FDA* (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

3. *Electronic online version of the FDA Orange Book* (<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

4. *USAN Stems* (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

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/s/  
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