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*APPLICATION NUMBER:*

**21-997**

**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: January 21, 2009

To: Russell Katz, MD, Director  
Division of Neurology Products

Thru: Kellié Taylor, PharmD, MPH, Team Leader  
Denise Toyer, PharmD, Deputy Director  
Carol Holquist, RPh, Director  
Division of Medication Error Prevention and Analysis

From: Melina Griffis, R.Ph, Safety Evaluator  
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name, Label, and Labeling Review

Drug Name: — (Zolpidem Tartrate Sublingual Tablets) **b(4)**  
5 mg, 10 mg

Application Type/Number: NDA 21-997

Applicant: Orexo AB

OSE RCM #: 2008-980

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22 Page(s) Withheld

6 Trade Secret / Confidential

       Draft Labeling

       Deliberative Process

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/s/

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Melina Griffis  
1/21/2009 03:29:43 PM  
DRUG SAFETY OFFICE REVIEWER

Kellie Taylor  
1/21/2009 03:42:46 PM  
DRUG SAFETY OFFICE REVIEWER

Denise Toyer  
1/22/2009 06:39:50 AM  
DRUG SAFETY OFFICE REVIEWER

Carol Holquist  
1/22/2009 09:06:19 AM  
DRUG SAFETY OFFICE REVIEWER