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APPLICATION NUMBER:
22-196

MEDICAL REVIEW(S)

CLINICAL REVIEW¹

Application Type 505 b (2) NDA
Submission Number 22196
Submission Code 000

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Reviewer Name June Cai, MD
Review Completion Date August 6, 2008

Established Name Zolpidem tartrate
(Proposed) Trade Name ZolpiMist™ Lingual Spray
Therapeutic Class Hypnotics
Applicant NovaDel Pharmaceuticals Inc.

Priority Designation S

Formulation Oral Spray
Dosing Regimen 5mg per spray:
-Adults: 10mg immediately before
bedtime
-Elderly: 5mg
-With hepatic impairment: 5mg
Indication Short-term treatment of insomnia
Intended Population Adults and elderly

¹ The new full NDA review template is applied to this review as instructed.

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Appears This Way
On Original

1 Recommendations/Risk Benefit Assessment

1.1 Recommendation on Regulatory Action

From clinical perspective, I recommend the Division taking an approval action for this NDA supplement if other aspects of data are sufficient, including inspection from the Agency Division of Scientific Inspection.

1.2 Risk Benefit Assessment

Despite potential risks, this application appears to demonstrate sufficient benefit outweighing risks if the data quality and reliability are sufficient.

1.3 Recommendations for Postmarketing Risk Management Activities

In addition to Medication Guide, periodic postmarketing surveillance for adverse events and abuse potential

(Cross-references: See also subsection 7.6.4 on page 19.)

b(4)

1.4 Recommendations for other Post Marketing Study Commitments

None from clinical point of view.

1.5 Other Phase IV Commitments

None from clinical point of view.

2 Introduction and Regulatory Background

2.1 Product Information

ZolpiMist™ is a new dosage and formulation of zolpidem tartrate (Ambien®) which chemical name is *N,N,6-trimethyl-2-p-tolylimidazo[1,2-a]pyridine-3-acetamide L-(+)-tartrate* (2:1), a non-benzodiazapine hypnotic of the imidazopyridine class.

It uses a metered dose oral spray delivery system that delivers a 5-mg dose of zolpidem tartrate in a 100uL spray. The sponsor states that one and two of actuations of ZolpiMist™ are intended to correspond with the 5- and 10 mg Ambien tablets. The indication for this product is for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

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