APPENDIX 1
RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S)

The goal of the REMS is to effectively communicate to patients the risks involved with Zolpimist® (zolpidem tartrate), 5mg and 10 mg oral spray (Zolpimist) and how to use Zolpimist safely.

II. REMS ELEMENTS

A. Medication Guide or PPI

A Medication Guide and Patient Instructions for Use will be dispensed with each Zolpimist prescription. Zolpimist is packaged as a single unit of use. The primary packaging of Zolpimist is a spray bottle that has a carton as the secondary packaging. The Zolpimist Medication Guide and Patient Instructions for Use are bar-coded to ensure the correct version is being used and then inserted into each carton. The carton, containing the Medication Guide and Patient Instructions for Use, will be provided directly to the patient at the time the prescription is dispensed by the pharmacy and requires no repackaging by the pharmacy. Thus, patients will automatically receive the Zolpimist Medication Guide and Patient Instructions for Use with their prescription.

B. Communication Plan

The REMS for Zolpimist does not include a Communication Plan.

C. Elements to Assure Safe Use

The REMS for Zolpimist does not include elements to assure safe use.

D. Implementation System

Because this REMS for Zolpimist does not include elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

The timetable for assessments of the Zolpimist REMS will be 18 months, 3 years, and 7 years after initial marketing approval of Zolpimist. NovaDel will submit the assessment within 60 days of the close of the assessment intervals noted above.