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**DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS**  
**PRELIMINARY CLINICAL SAFETY REVIEW OF NDA**

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**Brand Name:** Xyrem  
**Generic Name:** Sodium Oxybate  
**Sponsor:** Orphan Medical, Inc.  
**Indication:** Narcolepsy  
**NDA Number:** 21196  
**Original Receipt Date:** 10/3/00  
**Clinical Reviewer:** Ranjit B. Mani, M.D.  
**Review Author:** Ranjit B. Mani, M.D.  
**Review Completed:** 5/3/01

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