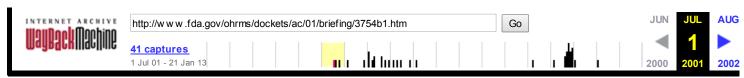
5/13/2014 PERIPHERAL



PERIPHERAL & CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE

June 6, 2001

Briefing Information

Consideratin of NDA 21-196, Xyrem (sodium oxybate, Orphan Medial Inc.), proposed to reduce the incidence of cataplexy and to improve the symptom of daytime sleepiness for persons wit narcolepsy.

Orphan Medical Presentations

Disclaimer

The statements contained in this document are those of the product's sponsor, not FDA, and FDA does not necessarily agree with the sponsor's statements. FDA has not made a final determination about the safety or effectiveness of the product described in this document.

Briefing Information pdf

Xyrem Prescription and Distribution Process, Video Script 2/2/01) html pdf

Video

FDA Briefing Information

Index pdf

Overview Memo pdf

Efficacy Review pdf

Safety Review pdf

Major Amendment Review pdf

Controlled Substance Overview pdf

