


INTERNET ARCHIVE
WayBackMachine

http://www.fda.gov/ohrms/dockets/ac/01/briefing/3754b1.htm

41 captures
1 Jul 01 - 21 Jan 13

JUN JUL AUG
2000 2001 2002



PERIPHERAL & CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE

June 6, 2001

Briefing Information

Consideration of NDA 21-196, Xyrem (sodium oxybate, Orphan Medical Inc.), proposed to reduce the incidence of cataplexy and to improve the symptom of daytime sleepiness for persons with 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](#)