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Jazz Pharma gets FDA nod for Xyrem to Treat Cataplexy and EDS

28 June 2018 | News

Jazz Pharmaceuticals Announces FDA Acceptance of Supplemental New Drug Application for Xyrem® (sodium oxybate) to Treat Cataplexy and Excessive Daytime Sleepiness in Pediatric Narcolepsy Patients

Jazz Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) accepted for priority review its supplemental new drug application (sNDA) seeking revised labeling for Xyrem® (sodium oxybate) oral solution, CIII, to include an indication to treat cataplexy and excessive daytime sleepiness (EDS) in pediatric narcolepsy patients. The Prescription Drug User Fee Act (PDUFA) goal date for an FDA decision is October 27, 2018.

"There has been a great deal of interest from the narcolepsy community in understanding the safety and efficacy of Xyrem in pediatric patients. We look forward to the FDA review and the potential for a new Xyrem indication specific to cataplexy and EDS in children and adolescents," said Jed Black, M.D., senior vice president, Sleep and CNS Medicine at Jazz Pharmaceuticals and adjunct professor, Stanford Center for Sleep Sciences and Medicine. "Jazz continues to strive to address unmet needs within the sleep community."