DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-196/S-009

Jazz Pharmaceuticals
Attention: Jennifer Ekelund, Director, Regulatory Affairs
3180 Porter Drive
Palo Alto, CA 94304

Dear Ms. Ekelund:

Please refer to your supplemental new drug application dated December 29, 2005, received December 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xyrem ® (sodium oxybate) oral solution.

We also refer to your new drug application for this drug product, which was reviewed and approved under the restricted distribution regulations contained in 21 CFR 314.500 (Subpart H) to assure safe use of the product.

This supplemental new drug application proposes to change the Xyrem Success Program® for Patients – Video Script. Specifically, the video script is being updated to reflect the approval of S-005 of this NDA, which expanded Xyrem's approved indications to include excessive daytime sleepiness. In addition, the text of the script has been altered to make it more clear and concise, as well as make the sequence of items contained in the text more logical.

We have completed our review of this application and have determined that the changes to the video script are acceptable. Accordingly, this application is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling script for use with your Xyrem Success Program® for Patients – Video.

We request that you submit a copy of the completed patient video when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jacqueline H. Ware, Pharm.D., Senior Regulatory Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research