DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-196/S-001

Orphan Medical
Attention: Dayton Reardan, Ph.D.
Vice President, Regulatory Affairs
13911 Ridgedale Drive, Suite 250
Minnetonka, MN 55305

Dear Dr. Reardan:

Please refer to your new drug application (NDA) dated August 8, 2002, received August 9, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xyrem® (sodium oxybate) Oral Solution.

We acknowledge receipt of your amendments dated August 13, September 4, September 30, 2002, April 14, September 5, and September 15, 2003.

This supplemental new drug application proposes revisions to the following:
1. Xyrem Physician Success Program
2. Xyrem Risk Management Program
3. Xyrem Post-Marketing Evaluation Program
4. Xyrem Prescription Form
5. Xyrem Patient Video Script

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon revisions. Accordingly, this application is approved effective on the date of this letter.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
11/4/03 11:10:03 AM