

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**021196Orig1s013**

*Trade Name:* Xyrem

*Generic or Established:* Sodium Oxybate

*Sponsor:* Jazz Pharmaceuticals

*Approval Date:* December 17, 2012

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## 021196Orig1s013

### CONTENTS

#### Reviews / Information Included in this NDA Review.

<b>Approval Letter</b>	<b>X</b>
<b>Other Action Letters</b>	
<b>Labeling</b>	<b>X</b>
<b>REMS</b>	
<b>Summary Review</b>	
<b>Officer/Employee List</b>	
<b>Office Director Memo</b>	
<b>Cross Discipline Team Leader Review</b>	
<b>Medical Review(s)</b>	<b>X</b>
<b>Chemistry Review(s)</b>	
<b>Environmental Assessment</b>	
<b>Pharm/Tox Review(s)</b>	
<b>Statistical Review(s)</b>	
<b>Microbiology Review(s)</b>	
<b>Clinical Pharm/Bio Review(s)</b>	
<b>Other Review(s)</b>	<b>X</b>
<b>Risk Assessment and Risk Mitigation Review(s)</b>	
<b>Proprietary Name Review(s)</b>	
<b>Administrative/Correspondence Document(s)</b>	

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*APPLICATION NUMBER:*

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**APPROVAL LETTER**



NDA 021196/S-013

**SUPPLEMENT APPROVAL**

Jazz Pharmaceuticals  
Attention: Jennifer Ekelund  
Executive Director, Regulatory Affairs  
3481 Porter Drive  
Palo Alto, CA 94304

Dear Ms. Ekelund:

We refer to your new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xyrem (Sodium Oxybate) 500 mg/ml oral solution.

Please refer to your Supplemental New Drug Application (sNDA) dated August 13, 2007, received August 15, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xyrem (Sodium Oxybate) 500 mg/ml oral solution.

We acknowledge receipt of your amendments dated February 3, 2011, April 24, 2012, and October 3, 2012.

This "Prior Approval" supplemental new drug application provides for compliance with the final rule, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products."

We have completed our review of this supplemental application, as amended and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

### **REPORTING REQUIREMENTS**

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 Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):

Content of Labeling  
Medication Guide

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