CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 21-196/S-019

Trade Name: Xyrem®

Generic Name: sodium oxybate

Sponsor: Jazz Pharmaceuticals

Approval Date: April 11, 2014

This "Prior Approval" supplemental new drug applications provide for the addition of information about drug reactions with ibuprofen, diclofenac and extended-release valproate to the "Dosage and Administration, "Drug Interactions", and "Clinical Pharmacology" sections of the labeling.

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APPROVAL LETTER

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21196/S-019

SUPPLEMENT APPROVAL

Jazz Pharmaceuticals
Attention: Joel Selcher, PhD
Senior Director, Regulatory Affairs
3180 Porter Drive
Palo Alto, CA 94304

Dear Dr. Selcher:

Please refer to your Supplemental New Drug Application (sNDA) dated June 18, 2013, received June 20, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xyrem (sodium oxybate) oral solution.

We acknowledge receipt of your amendments dated November 25, 2013, and January 27, 2014.

This "Prior Approval" supplemental new drug application provides for the addition of information about drug reactions with ibuprofen, diclofenac, and extended-release valproate to the "Dosage and Administration", "Drug Interactions", and "Clinical Pharmacology" sections of the labeling.

APPROVAL & LABELING

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 and 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

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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 that includes labeling changes 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).

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}

Eric Bastings, MD
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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