NDA 021196/S-031

APPROVAL LETTER

Jazz Pharmaceuticals, Inc.
Attention: Wheatley Spence
Director, Regulatory Affairs
2005 Market Street, 21st Floor
Philadelphia, PA 19103

Dear Ms. Spence:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 11, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for XYREM (Sodium oxybate) Oral Solution, 500 mg/mL.

This Prior Approval supplemental new drug application provides for:

1. The introduction of a new 6 oz (2-piece) amber bottle comprised of an (b) (4) and an (b) (4) base cup,
2. Addition of a press-in bottle adaptor (PIBA), and
3. Addition of updates to the labeling associated with the proposed changes in the container closure system.

APPROVAL & LABELING

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

CONTAINER LABELS

Submit final printed container labels that are identical to carton and immediate container labels submitted on January 15, 2019, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Product Correspondence – Final Printed Container Labels for approved NDA 021196/S-031.**" Approval of this submission by FDA is not required before the labeling is used.

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

If you have any questions, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

For
David Lewis,
Acting Branch Chief
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Container Labeling