CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

212690Orig1s000

Trade Name:	Xywav oral solution
Generic or Proper Name:	calcium, magnesium, potassium, and sodium oxybates
Sponsor:	Jazz Pharmaceuticals, Inc.
Approval Date:	July 21, 2020
Indication:	provides for the use of Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution, 0.5 g/mL, for treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

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APPROVAL LETTER

NDA 212690

NDA APPROVAL

Jazz Pharmaceuticals, Inc.
Attention: Arthur Merlin d'Estreux
Director, Global Regulatory Lead
2005 Market Street, Suite 2100
Philadelphia, PA 19103

Dear Mr. d'Estreux:

Please refer to your New Drug Application (NDA) dated January 21, 2020, received January 21, 2020, and your amendments, submitted under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution.

This new drug application provides for the use of Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution, 0.5 g/mL, for treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling, unless we notify you otherwise.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible via publicly available labeling repositories.

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on June 19, 2020, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 212690**." Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for Xywav was not referred to an FDA advisory committee because there were no issues with this application that would benefit from advisory committee discussion.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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