CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212690Orig1s000

OTHER REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	July 7, 2020
To:	Vandna Kishore Regulatory Project Manager **Division of Neurology I**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** Marcia Williams, PhD Team Leader, Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Lonice Carter, MS, RN, CNL Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Rebecca Falter, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Medication Guide (MG) and Instructions for Use (IFU)
Drug Name (established name):	XYWAV (calcium oxybate, potassium oxybate, magnesium oxybate, sodium oxybate)
Dosage Form and Route:	oral solution, CIII
Application Type/Number:	NDA 212690
Applicant:	Jazz Pharmaceuticals

1 INTRODUCTION

On January 21, 2020, Jazz Pharmaceuticals submitted for the Agency's review an original New Drug Application (NDA) 212690 for XYWAV (calcium oxybate, potassium oxybate, magnesium oxybate, sodium oxybate). This NDA proposes the indication for the treatment of cataplexy and excessive daytime sleepiness in patients 7 years of age and older with narcolepsy. The reference listed drug for this NDA is XYREM (sodium oxybate).

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Neurology I on February 4, 2020 and February 5, 2020, for DMPP and OPDP to review the Applicant's proposed Medication Guide (MG), and Instructions for Use (IFU) for XYWAV (calcium oxybate, potassium oxybate, magnesium oxybate, sodium oxybate) oral solution, CIII.

2 MATERIAL REVIEWED

- Draft XYWAV (calcium oxybate, potassium oxybate, magnesium oxybate, sodium oxybate) MG and IFU received on January 21, 2020, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on June 22, 2020.
- Draft XYWAV (calcium oxybate, potassium oxybate, magnesium oxybate, sodium oxybate) Prescribing Information (PI) received on January 21, 2020, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on June 22, 2020.
- XYREM (sodium oxybate) comparator labeling dated October 26, 2018.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level. In our review of the MG and IFU the target reading level is at or below an 8th grade level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss.

In our collaborative review of the MG and IFU we:

- simplified wording and clarified concepts where possible
- ensured that the MG and IFU are consistent with the Prescribing Information (PI)

- removed unnecessary or redundant information
- ensured that the MG and IFU are free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the MG meets the Regulations as specified in 21 CFR 208.20
- ensured that the MG and IFU meet the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)
- ensured that the MG and IFU are consistent with the approved comparator labeling where applicable.

4 CONCLUSIONS

The MG and IFU are acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the MG and IFU is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the MG and IFU.

Please let us know if you have any questions.

18 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LONICE J CARTER
07/07/2020 07:47:45 AM

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07/07/2020 08:03:39 AM

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