CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211150Orig2s000

OTHER REVIEW(S)

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: October 8, 2020

To: Martine Solages, Clinical Reviewer
Division of Psychiatry (DP)

Jasmeet (Mona) Kalsi, Regulatory Project Manager, DP

Kimberly Updegraff , Associate Director for Labeling, DP

From: Christine Bradshaw, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Aline Moukhtara, Team Leader, OPDP

Subject: OPDP Labeling Comments for Wakix (pitolisant) tablets

NDA: 211150/Class 1 NDA resubmission

In response to DP's consult request dated September 3, 2020, OPDP has completed a focused review of sections 1, 4, 14, and 17 of the proposed product labeling (PI), for the Class 1 NDA resubmission for Wakix.

Labeling: OPDP's comments on the proposed labeling are based on the draft labeling received by electronic mail from DP (Updegraff) on October 2, 2020, and are provided below.

Thank you for your consult. If you have any questions, please contact Christine Bradshaw at (301) 796-6796 or Christine.Bradshaw@fda.hhs.gov.

19 Page(s) of Draft Labeling have been Withheld in Full as B4 (CCI/TS) immediately following this page

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/s/

CHRISTINE J BRADSHAW
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FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: July 12, 2019

To: Brendan Muoio, Regulatory Project Manager
Division of Psychiatry Products (DPP)

Kimberly Updegraff, Associate Director for Labeling, DPP

From: Dhara Shah, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Aline Moukhtara, Team Leader, OPDP

Subject: OPDP Labeling Comments for WAKIX® (pitolisant) tablets, for oral use

NDA: 211150 O-1 & O-2

In response to DPP's consult request dated January 14, 2019, OPDP has reviewed the proposed product labeling (PI) and carton and container labeling for the original NDA submission for Wakix.

PI: OPDP's comments on the proposed labeling are based on the draft PI received by electronic mail from DPP (Brendan Muoio) on July 5, 2019, and are provided below.

Carton and Container Labeling: OPDP has reviewed the attached proposed carton and container labeling submitted by the Sponsor and received by electronic mail from DPP (Brendan Muoio) on July 8, 2019, and we do not have any comments.

Thank you for your consult. If you have any questions, please contact Dhara Shah at (240) 402-2859 or Dhara.Shah@fda.hhs.gov.

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/s/

DHARA SHAH
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