CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209080Orig1s000

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:	August 1, 2018
To:	Billy Dunn, MD Director **Division of Neurology Products (DNP)**
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:	Karen Dowdy, RN, BSN Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Sapna Shah, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Instructions for Use (IFU)
Drug Name (established name):	TIGLUTIK (riluzole)
Dosage Form and Route:	oral suspension
Application Type/Number:	NDA 209080
Applicant:	DJA Global Pharmaceuticals Inc, Authorized U.S. Agent for Italfarmaco S.p.A.

1 INTRODUCTION

On November 16, 2017, DJA Global Pharmaceuticals Inc, Authorized U.S. Agent for Italfarmaco S.p.A., submitted for the Agency's review a 505(b)(2) New Drug Application (NDA) 209080 for TIGLUTIK (riluzole) oral suspension. The Reference Listed Drug is RILUTEK (riluzole) tablets NDA 020599. The proposed indication for TIGLUTIK (riluzole) oral suspension is for the treatment of amyotrophic lateral sclerosis (ALS).

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to requests by the Division of Neurology Products (DNP) on December 1, 2017 for DMPP and OPDP to review the Applicant's proposed Instructions for Use (IFU) for TIGLUTIK (riluzole) oral suspension.

DMPP conferred with the Division of Medication Error Prevention and Analysis (DMEPA) and a separate DMEPA review of the IFU was completed on March 21, 2018.

2 MATERIAL REVIEWED

- Draft TIGLUTIK (riluzole) oral suspension IFU received on July 13, 2018, and received by DMPP on July 13, 2018.
- Draft TIGLUTIK (riluzole) oral suspension IFU received on July 13, 2018 and received by OPDP on July 18, 2018.
- Draft TIGLUTIK (riluzole) oral suspension Prescribing Information (PI) received on November 16, 2017, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on July 18, 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.

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. We reformatted the IFU document using the Arial font, size 11.

In our collaborative review of the IFU we:

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

- removed unnecessary or redundant information
- ensured that the IFU is free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the IFU meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The IFU is 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 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 IFU.

Please let us know if you have any questions.

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

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/s/

KAREN M DOWDY
08/01/2018

SAPNA P SHAH
08/02/2018

MARCIA B WILLIAMS
08/02/2018

LASHAWN M GRIFFITHS
08/02/2018

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

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

Memorandum

Date: July 27, 2018

To: Teresa Buracchio, M.D.
Division of Neurology Products (DNP)

Brenda Reggettz, PharmD, Regulatory Project Manager, (DNP)

Tracey Peters, PharmD, Associate Director for Labeling, (DNP)

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

CC: Aline Moukhtara, RN, MPH, Acting Team Leader, OPDP

Subject: OPDP Labeling Comments for TIGLUTIK™ (riluzole) oral suspension

NDA: 209080

In response to the DNP consult request dated December 1, 2017, OPDP has reviewed the proposed product labeling (PI), Instructions for Use (IFU), and carton and container labeling for the original NDA submission for TIGLUTIK™ (riluzole) oral suspension (Tiglutik).

PI: OPDP's comments on the proposed labeling are based on the draft PI received by electronic mail from DNP (Brenda Reggettz) on July 18, 2018, and are provided below.

IFU: A combined OPDP and Division of Medical Policy Programs (DMPP) review will be completed, and comments on the proposed IFU will be sent under a separate cover.

Carton and Container Labeling: OPDP has reviewed the attached proposed carton and container labeling submitted by electronic mail from DNP on July 18, 2018, and we do not have any comments.

Thank you for your consult. If you have any questions, please contact Sapna Shah (240) 402-6068 or Sapna.Shah@fda.hhs.gov.

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/s/

SAPNA P SHAH
07/27/2018

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	July 20, 2018
Requesting Office or Division:	Division of Neurology Products
Application Type and Number:	NDA 209080
Product Name and Strength:	Tiglutik (riluzole) oral suspension 50 mg/10 mL
Applicant/Sponsor Name:	Italfarmaco S.p.A.
FDA Received Date:	July 20, 2018
OSE RCM #:	2017-2447-2
DMEPA Safety Evaluator:	Briana Rider, PharmD
DMEPA Team Leader:	Lolita White, PharmD

1 PURPOSE OF MEMORANDUM

The Division of Neurology Products requested that we review the revised container label and carton labeling for Tiglutik (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The revised container label and carton labeling for Tiglutik are acceptable from a medication error perspective. We have no further recommendations at this time.

[a] Rider B. Label and Labeling Review Memo for Tiglutik (NDA 209080). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JUL 12. RCM No.:2017-2447-1.

APPENDIX A. IMAGES OF LABEL AND LABELING RECEIVED ON JULY 20, 2018

Container labels

(b) (4)

Carton labeling

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/s/

BRIANA B RIDER
07/20/2018

LOLITA G WHITE
07/20/2018

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 2/26/2018

TO: Division of Neurology Products
Office of Drug Evaluation I

FROM: Division of New Drug Bioequivalence Evaluation (DNDBE)
Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Recommendation to accept data without an on-site inspection**

RE: NDA 209080

The Division of New Drug Bioequivalence Evaluation (DNDBE) within the Office of Study Integrity and Surveillance (OSIS) recommends accepting data without an on-site inspection. The rationale for this decision is noted below.

Rationale

OSIS recently inspected the site listed below. The inspectional outcome from the inspections was classified as No Action Indicated (NAI).

Inspection Site

Facility Type	Facility Name	Facility Address
Analytical	(b) (4)	
Clinical	InVentiv Health Clinique, Inc.	2500 Rue Einstein, Quebec City, Quebec, Canada

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/s/

SHILA S NKAH
02/26/2018