NDA 204447/S-021
NDA 204447/S-022

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Takeda Pharmaceuticals, USA, Inc.
Attention: Kinnari Shah
Sr. Manager, Global Regulatory Affairs Marketed Products
40 Landsdowne Street
Cambridge, MA 02139

Dear Ms. Shah:

Please refer to your supplemental new drug applications (sNDA) dated and received July 24, 2020 (NDA 204447/S-021) and December 22, 2020 (NDA 204447/S-022) in addition to your amendments submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trintellix (vortioxetine) tablets.

NDA 204447/S-021

This Prior Approval supplemental new drug application provides for the addition of safety information in pediatric patients ages 12 to 17 years with Major Depressive Disorder.

NDA 204447/S-022

This Prior Approval supplemental new drug application provides for an addition to the Drug Interactions section of the Prescribing Information to include information about false positive result in urine immunoassays for methadone. The supplement also provides for the addition of "headache," "hyperhidrosis," and "hyperprolactinemia" to the Adverse Reactions Postmarketing Experience section.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 none of these criteria apply to your application, you are exempt from this requirement.

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

FULFILLMENT OF POSTMARKETING REQUIREMENT

Your July 24, 2020, submission contains the final report for the following postmarketing commitment listed in the September 30, 2013 approval letter and June 18, 2018 new postmarketing requirement letter.

2084-8 Deferred pediatric study under PREA for the treatment of major depressive disorder in adolescents aged 12 to17 years. Conduct a study to obtain data on the efficacy and safety of vortioxetine in the relevant pediatric population. This must be a placebo-controlled study. This study must be a fixed-dose study.

We have reviewed your submission and conclude that the above commitment was fulfilled.

We remind you that there is a postmarketing requirement listed in the September 30, 2013, approval letter and June 18, 2018, new postmarketing requirement letter that is still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call ShinYe (Sandy) Chang, Senior Regulatory Project Manager, at ShinYe.Chang@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tiffany R. Farchione, M.D.
Director
Division of Psychiatry
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

TIFFANY R FARCHIONE
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