March 23, 2015

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

Mitchell Mathis, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Psychiatry Products
5901-B Ammendale Rd
Beltsville, MD 20705-1266

Attn: Hiren Patel, PharmD, Regulatory Project Manager
CC: CDER's Pediatric and Maternal Health Staff

Re: NDA 204-447/ SEQUENCE NO: 0075
Brintellix (vortioxetine) Tablets

Dear Dr. Mathis:

Takeda Development Center Americas, Inc. (Takeda), on behalf of Takeda Pharmaceuticals U.S.A. (TPUSA), submits this postmarketing correspondence under the provisions of section 505B of the Federal Food, Drug and Cosmetic Act. Reference is made to NDA 204-447 for Brintellix (vortioxetine) Tablets and approval letter dated September 29, 2013. Reference is also made to the Notification of Non-compliance with PREA dated March 10, 2015.

Deferral Extension Requested

Takeda and partner, H. Lundbeck A/S (Lundbeck), remain committed to completing a pediatric program that provides clinically meaningful information on the use of vortioxetine in pediatric patients. Takeda acknowledges the delay to PMR 2084-1and failure to submit the final report by February 2015. Takeda notes that a status update and request for guidance was sent via email to Hiren Patel, FDA on November 25, 2014. As detailed in this email, as well as the NDA Annual Report (Sequence 0068) submitted on November 26, 2014, recruitment of the last cohort of Study 12708A was more difficult than anticipated (based on enrollment of prior cohorts), despite significant and sustained actions aiming to encourage enrollment. However, currently all subjects have completed the study and the final report is being drafted. Takeda respectfully requests a Deferral Extension to PMR 2084-1 allowing for submission of the final report by April 30, 2015. Delays encountered during the conduct of PMR 2084-1 are not currently anticipated to impact commitment dates for the remainder of the pediatric program (PMR 2084-2 and PMR 2084-3).

The vortioxetine pediatric studies are conducted under the Lundbeck sponsored IND 112,581. As requested, a letter of cross-reference to this submission will be filed to IND 112,581. In addition, a copy will be sent to CDER's Pediatric and Maternal Health Staff.

This submission is submitted in electronic Common Technical Document (eCTD) format and is approximately 1 MB. Files were scanned using Symantec Endpoint Protection, Version 12.1.2015.2015, to ensure the submission is virus free.

Takeda Development Center Americas, Inc.
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If you have any technical questions regarding this eCTD submission, you may contact Janis Gyzen, Associate Director, Publishing and Submission Support at (224) 554-2086 (office) or (847) 830-7833 (mobile) or janis.gyzen@takeda.com.

Please do not hesitate to contact me if you have any additional questions.

Sincerely,

Joanna Sambor - Laura Schraven for

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