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August 3, 2018

Mitchell V. Mathis, M.D.
Director, Division of Psychiatry Products (DPP)
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

NDA: **022567 – Viibryd (vilazodone hydrochloride) 10 mg, 20 mg, and 40 mg Tablets**
Re: **RESPONSE TO PREA NON-COMPLIANCE LETTER FOR PMR 1723-12**
DEFERRAL EXTENSION REQUESTED: PMR 1723-12 (STUDY VLZ-MD-21) AND PMR 1723-3 (STUDY VLZ-MD-22)
Seq. No.: **0142**

Dear Dr. Mathis,

Reference is made to NDA 022567 for Viibryd (vilazodone hydrochloride) 10 mg, 20 mg and 40 mg tablets approved on January 21, 2011.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], Allergan is responding to the Notification of Non-Compliance with Pediatric Research Equity Act (PREA) letter dated July 06, 2018 and requesting a Deferral Extension for PMR 1723-12 and PMR 1723-3.

Allergan would like to reaffirm its commitment to fulfill all outstanding PREA PMR studies for Viibryd and to respond specifically to FDA's non-compliance letter referenced above for VLZ-MD-21 (PMR 1723-12).

Further reference is made to the postmarketing requirement (PMR) 1723-12 (Study VLZ-MD-21) pediatric study under PREA issued on January 17, 2018, also conducted to satisfy the Pediatric Written Request (PWR) study #1 issued on November 20, 2012. PMR 1723-12 final study report under PREA for this application was submitted to the NDA on June 25, 2018 (Seq. 0141).

On January 17, 2018, the Sponsor was issued a new PMR 1723-12 and released from PREA PMR 1723-2 under the approval letter dated January 21, 2011. Study VLZ-MD-21 was conducted only in pediatric patients aged 12 to 17 and does not include an active control (fluoxetine).

Reference is made to the new Postmarketing requirement:

1723-12 Deferred pediatric study under PREA for the treatment of major depressive disorder in pediatric patients aged 12 to 17. Conduct a study to obtain data on the efficacy and safety of vilazodone in the relevant pediatric population. This must be a placebo-controlled study. This study must be a fixed-dose study.

Final Report Submission Due: June 28, 2018

Allergan submitted the final report for Study VLZ-MD-21 on June 25, 2018 to satisfy/fulfill the PREA PMR submission deadline. VLZ-MD-21 was designed to fulfill both PMR 1723-12 and PWR Study # 1. Proposed labeling were not submitted at the time since our submission plan is to associate the supplement in relations to the PWR for Viibryd to be submitted by October 19, 2019. On April 09, 2018, the Sponsor submitted a deferral extension for PMR 1723-3 (granted May 25, 2018) and proposed modifications to the PWR issued on November 20, 2012. The Sponsor reached agreement on the PWR modifications and the Written Request – Amendment 1 was granted on July 18, 2018.

Pediatric Research Equity Act (PREA) Studies:

- VLZ-MD-21 (PMR 1723-12): conducted in adolescents aged 12-17 for safety and efficacy: placebo-controlled – completed
  - Final Study Report due June 28, 2018
  - Final Report Submitted on June 25, 2018
- VLZ-MD-22 (PMR 1723-3): conducted in children and adolescents aged 7-17 for safety and efficacy: placebo and active controlled - on-going
  - Deferral extension granted for June 30, 2019

PWR Submission Studies:

- PREA studies listed above are associated with PWR Study 1 (VLZ-MD-21) and Study 2 (VLZ-MD-22)
- Study 3 (VLZ-MD-23): open label safety study conducted in children and adolescents aged 7-17 - on-going
- PWR timeframe for submitting all three reports as supplement to NDA on or before October 19, 2019

The Sponsor would like to request a deferral extension for PMR 1723-12 (study VLZ-MD-21) to delay labeling updates until additional safety or effectiveness data have been collected from on-going studies VLZ-MD-22 (PMR 1723-3) and VLZ-MD-23 (PWR Study #3). The above-mentioned studies include the relevant pediatric population from VLZ-MD-21 (aged 12-17). In addition, we would like to request a deferral extension for PMR 1723-3 (Study VLZ-MD-22). Allergan is committed to submitting an sNDA to include all safety and efficacy data from all three studies to appropriately update the Prescribing Information (PI). The Sponsor proposal is to align PREA PMR 1723-12 and 1723-3 final report timelines with the revised PWR submission date of October 19, 2019. The deferral extension request is provided in Module 1.9.2.

Allergan considers this information to be confidential and not publicly disclosable in accordance with 21 CFR 314.430. If you have any questions related to this submission, please do not hesitate to contact me at (201) 386-2015, or in my absence Michael K. Olchaskey, PharmD, at (201) 386-2142 or via email at *michael.olchaskey@allergan.com*.

Sincerely,

Nadia C. Success
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