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ESG

**RESPONSE TO PREA NON-COMPLIANCE LETTER -
DEFERRAL EXTENSION REQUESTED**

Submission date: May 10, 2023

Jessica Lee, MD., Director
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 208745: TRLUANCE® (plecanatide) tablets, 3 mg
Sequence 0436: Response to PREA Non-compliance Letter- Deferral Extension Requested

Dear Dr. Lee:

Reference is made to the NDA 208745 for Trulance® (plecanatide) tablets, 3 mg for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation in adults.

Reference is also made to the FDA letter - Notification of Non-compliance with PREA dated March 31, 2023 (Reference ID: 5151111) for the below postmarketing studies:

3117-4 Determine the appropriate Trulance (plecanatide) treatment dose for pediatric patients with chronic idiopathic constipation (CIC) who are 2 years to less than 6 years of age by assessing the safety and efficacy of once daily oral plecanatide in an eight (8) week, proof-of-concept, dose-ranging with sparse pharmacokinetic (PK) sampling study.

And

3304-2 Confirm the efficacy and safety of Trulance (plecanatide) treatment in pediatric patients with IBS-C who are 6 years to less than 18 years of age by performing a randomized, double-blind, placebo-controlled, parallel group, 12-week treatment study. Patients will be stratified by age (6 years to 11 years and 12 years to less than 18 years of age).

The purpose of this submission is to provide a formal response to the above referenced PREA Non-compliance letter which can be found in Section 1.17.2 Correspondence Regarding Postmarketing Requirements. The response includes explanation for the delay and deferral extension request for the dose finding study PMR 3117-4 and the following confirmatory study PMR 3117-5 in children 2 years to less than 6 years of age for FDA consideration.

Additionally, a change in alternative regulatory contact for this application is provided in Section 1.3.1.2 Change in Contact/Agent.

This submission is provided in electronic Common Technical Document format and is approximately 4 MB in size. The content of the submission has been verified to be free of viruses using the latest version of Carbon Black Defense. The submission is being provided via the FDA's Electronic Submission Gateway. Please note that a letter of non-repudiation dated November 16, 2022 is on file with the Agency.

The information contained in this submission is confidential and as such should be handled in accordance with the provisions established in 21 CFR §314.430.

Should you have any questions or comments regarding this submission, please do not hesitate to contact me. Alternatively, you may contact Sean Humphrey, Senior Director of Global Regulatory Affairs at (707) 796-7222 or by email at Sean.Humphrey@bauschhealth.com.

Sincerely,

Mercy James

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