Bausch Health US, LLC
400 Somerset Corporate Boulevard
Bridgewater NJ 08807
Tel.: 908-927-1400
www.bauschhealth.com

RESPONSE TO PREA NONCOMPLIANCE LETTER

ESG

Submission date: December 23, 2024

Jessica J. Lee, MD, Director
Division of Gastroenterology
Food and Drug Administration
Center for Drug Evaluation and Research
Attention: Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 208745: TRLUANCE® (plecanatide) tablets, 3 mg
Product Correspondence – PMR 3304-1- Response to PREA Noncompliance Letter - Deferral Extension Requested
Sequence 0446

Dear Dr. Lee:

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

Reference is also made to the below deferred pediatric study communicated as required post-marketing study with the approval of TRULANCE NDA 208745 Supplement (S-001) for the addition of IBS-C indication. Reference is also made to the Deferral Extension Request filed on November 19, 2024 (Sequence 0444) and to the FDA Notification of Non-Compliance with PREA letter dated December 06, 2024 (Reference ID: 5491818) for this study.

3304-1: Perform a double-blind, dose ranging study in pediatric patients ages 6 years to less than 18 years in order to evaluate the safety and efficacy of once daily oral Trulance (plecanatide) for 4 weeks as treatment of IBS-C. Patients will be stratified by age group (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. The Sponsor makes reference to Section 1.17.2 Correspondence Regarding Postmarketing Requirements that was submitted in Sequence 0444 which includes explanation for the delay of the study and request for deferral extension for FDA consideration.

This submission is provided in the electronic Common Technical Document format and is approximately 3 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

Digitally signed by Mercy James
Date: 2024.12.19 00:40:37
+05'30'

BAUSCH Health

Mercy James, Ph.D., RAC
Director, Global Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807
Mercy.James2@bauschhealth.com
Mobile Phone: 609-455-0813