Salix Pharmaceuticals, Inc.

BAUSCH Health

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

ESG

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

Submission date: August 3, 2022

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: TRULANCE® (plecanatide) tablets, 3 mg
Sequence 0428: 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 June 23, 2022 for the below postmarketing studies:

3117-2: Determine the appropriate Trulance (plecanatide) treatment dose for pediatric patients with chronic idiopathic constipation (CIC) who are 6 years to less than 12 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

3117-3: Confirm the efficacy and safety of Trulance (plecanatide) in pediatric patients with chronic idiopathic constipation (CIC) 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.

The purpose of this submission is to provide a formal response to the above referenced PREA Non-compliance letter. As part of this response, provided in Section 1.17.2 Correspondence Regarding Postmarketing Requirements of this submission includes explanation for the delay of the studies and deferral extension requested with justification for extension of study completion and report submission for FDA consideration.

This submission is provided in 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 January 13, 2015 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 Deborah Panei, Sr. Manager, Global Regulatory Affairs by mobile phone at 908-381-4945 or by email at Debbie.Panei@bauschhealth.com.

Sincerely,

Mercy James Digitally signed by mercy.james1
Date: 2022.07.27 11:02:30 -05'00'

Mercy James, Ph.D., RAC
Director, Global Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807
mercy.james2@bauschhealth.com
Phone: 609-455-0813
BAUSCH Health