NDA 208745/S-001

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Salix Pharmaceuticals, Inc.
Attention: Mercy James, PhD, RAC
Senior Director, Global Regulatory Affairs
400 Somerset Corporate Blvd
Bridgewater, NJ 08807

Dear Dr. James:

Please refer to your supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Trulance (plecanatide) tablet, which was approved on January 24, 2018.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for the following PMR:

PMR 3304-1, which was deferred until July 31, 2024.

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)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response. We note that you requested a deferral extension for PMR 3304-1 on November 19, 2024, which is still under review. In your response to this letter, you may refer to the Deferral Extension Request that is currently under review; a new request with the same information that has already been submitted is not necessary.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your sNDA

with a cross-reference letter to the Investigational New Drug Application (IND) to which your protocol has been submitted.

If you have any questions, contact Kristina Luong, Senior Regulatory Health Project Manager, at 301-348-3950 or Kristina.Luong@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Juli Tomaino, MD, MS
Deputy Director
Division of Gastroenterology
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JULI A TOMAINO
12/06/2024 05:18:32 PM