



NDA 208745
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 new drug application (NDA) and 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 19, 2017 and January 24, 2018, respectively.

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 PMRs:

PMR 3117-4, which was due by February 28, 2023
PMR 3304-2, which was due by November 30, 2022

Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

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 3304-2 on February 23, 2023, which we granted on March 30, 2023.

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.

NDA 208745
NDA 208745/S-001
Page 2

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, call Kristina Luong, Regulatory Project Manager, at (301) 348-3950.

Sincerely,

{See appended electronic signature page}

Jessica J. Lee, MD, MMSc
Director
Division of Gastroenterology
Office of Immunology and Inflammation
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/

JESSICA J LEE
03/31/2023 08:52:33 AM