NDA 021361/S-012

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Salix Pharmaceuticals, Inc.
Attention: Libette Luce, MA
Senior Director, Global Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, NJ, 08807

Dear Ms. Luce:

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 Xifaxan (rifaximin) tablets, 200 mg and 550 mg, which was approved on May 27, 2015.

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 PMR 2900-1, which was deferred until March 31, 2019.

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 on April 12, 2019; however, we have determined that your request did not qualify for an extension.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm 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, call CDR Andrew Nyabwari, Program Coordinator, at (240) 402-0075.

Sincerely,

{See appended electronic signature page}

Dragos Roman, MD
Director (Acting)
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
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/

DRAGOS G ROMAN
08/21/2019 04:42:46 PM