Salix
PHARMACEUTICALS, INC.

July 25, 2013

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

Donna Griebel, MD
Director
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Food and Drug Administration
Center for Drug Evaluation and Research
Attention: Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 22-301, Sequence 0004
Apriso® (Mesalamine) Extended-Release Capsules, 0.375 g
Response to PREA Non-Compliance Letter and Deferral Extension Request

Dear Dr. Griebel:

Reference is made to NDA 22-301 for Apriso® (mesalamine) Extended-Release Capsules, 0.375 g approved on October 31, 2008 and the deferred pediatric study under the Pediatric Research Equity Act (PREA) for patients ages 5 to 17 years. Further reference is made to the "Notification of Non-Compliance with PREA" letter dated June 10, 2013 for APRISO in which the FDA requested a response from Salix Pharmaceuticals, Inc. (Salix) within 45 calendar days.

The purpose of this submission is to respond to the Agency's letter dated June 10, 2013 and to request a deferral extension for the required pediatric study for Apriso. Salix is fully committed to advancing research in pediatric gastroenterology and in completing its commitment to conduct a study to assess the efficacy of Apriso in ulcerative colitis patients aged 5 to 17 years. We have worked closely with leading pediatric gastroenterologists to optimize our study protocol; and unfortunately, it has taken longer than expected to develop an appropriate study design, pediatric-feasible drug formulation, and dosing regimen for mesalamine granules in pediatric patients. The revised draft study protocol and responses to FDA comments are being submitted to IND 62,113 (Serial No. 0084, Seq. No. 0004) in parallel with this correspondence.

For these reasons, Salix requests a deferral extension for the required pediatric study. (b) (4)

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Salix appreciates the Agency's consideration of a deferral extension.

This submission is compliant with FDA's "Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)". All files were checked and verified to be free of viruses before being sent through the FDA Electronic Submissions Gateway, using Micro OfficeScan, version 10, service pack 1.

The IT point of contact for this submission is Steven Smith (telephone: (919) 447-3488; email: Steven.Smith@Salix.com).

If there are any questions concerning this submission, please contact me by phone at 919-447-3404 or by email at Benjamin.Burgin@Salix.com.

Sincerely,

Benjamin M. Burgin, RAC
Associate Director, Regulatory Affairs
Salix Pharmaceuticals, Inc.

cc: Lynne P. Yao, M.D.
Associate Director (Acting)
Pediatric and Maternal Health Staff
Office of New Drugs, CDER