VALEANT
Pharmaceuticals North America LLC

Salix
PHARMACEUTICALS, INC.

Jennifer S. Knicley, MS
Senior Manager, Regulatory Affairs

400 Somerset Corporate Boulevard, Bridgewater, NJ 08807
Tel: 908-927-1400
Email: Jennifer.Knicley@bausch.com
www.valeant.com

RESPONSE TO PREA NON-COMPLIANCE LETTER

ESG

Donna Griebel, M.D., Director
Division of Gastroenterology and Inborn Errors Products
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 203634 – Uceris (budesonide) Extended-Release Tablets, 9 mg
Product Correspondence: Response to PREA Non-Compliance Letter
Sequence No. 0089

Dear Dr. Griebel:

Reference is made to NDA 203634 for Uceris (budesonide) Extended-Release Tablets, 9 mg approved on January 14, 2013. The NDA approval letter included the following deferred pediatric study as a postmarketing requirement under the Pediatric Research Equity Act (PREA):

> **1997-1:** An 8-week randomized, double blind, placebo-controlled trial in children 5 to 17 years of age with active, mild to moderate ulcerative colitis. The trial will evaluate pharmacokinetics (PK), efficacy for induction of remission, and safety of at least 2 doses of Uceris (budesonide). The effects of 8 weeks of Uceris (budesonide) on the HPA axis will be assessed.

Additional reference is made to the Deferral Extension Request submitted on June 9, 2016 and to the Agency's subsequent Deferral Extension Denial on July 25, 2016 and Notification of Non-Compliance with PREA letter dated October 4, 2016.

The purpose of this communication is to respond to the notification of non-compliance letter with our plan to address the outstanding assessment. For the reasons previously described in the deferral extension request, development of the protocol has been delayed. Based on the discussions with the Agency regarding the study design during the pre-IND meeting (PIND 118972), the protocol has been revised and will be submitted to IND 074882 for the Agency's review.

The sponsor is fully committed to completing the necessary steps to fulfill this requirement and proposes the following revised timetable for completion of activities. We appreciate the Division's consideration of this proposal and willingness to work with us on the study design.

	Final Protocol Submission	Trial Completion	Final Report Submission
Original Timeline	09/2013	06/2016	09/2016
Proposed Timeline	(b) (4)		

*Draft protocol to be submitted for review by (b) (4). Timeline of final protocol is to allow for discussion and to ensure alignment on study design.

This submission is provided in electronic Common Technical Document (eCTD) format and is approximately 2 MB in size. The content of the submission has been verified to be free of viruses using the latest version of McAfee VirusScan Enterprise. The submission is being provided via the FDA's Electronic Submission Gateway (ESG). 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. Alternately, you may contact Isabelle B. Lefebvre, MSc, RAC (EU & US), Vice President, US Regulatory Affairs, by telephone at 908-541-3065 or by email at isabelle.lefebvre@valeant.com.

Sincerely,

Knicley, Jennifer S

Digitally signed by Knicley, Jennifer S
DN: cn=Knicley, Jennifer S, email=Jennifer.Knicley@bausch.com
Date: 2016.11.18 07:10:53 -05'00'

Jennifer S. Knicley, MS
Senior Manager, US Regulatory Affairs
Telephone: 585-338-6307
Mobile: 585-764-6577
Email: Jennifer.Knicley@bausch.com