DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205613

TENTATIVE APPROVAL

Salix Pharmaceuticals, Inc.
Attention: Jennifer Richards
Associate Director, Regulatory Affairs
8510 Colonnade Center Drive
Raleigh, NC 27615

Dear Ms. Richards:

Please refer to your New Drug Application (NDA) dated November 15, 2013, received November 15, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Uceris (budesonide) rectal foam, 2 mg.

We acknowledge receipt of your amendments dated December 16, 2013, January 13, 24, 28, 2014, February 05, 14, 18, 25, 27, 2014, March 05, 07, 18, 26(2), 2014, April 09, 15, 22, 30, 2014, May 12, 19, 23, 29, 2014, June 03, 04, 17(2), 25, 2014, July 02, 08, 10(2), 14, 15, 18, 22(3), 28, 31, 2014, August 07, 08, 15, 18(2), 22, 25, 26, 27, and September 03, 05(2), 08, 10, 11, 12, 2014.

This NDA provides for the use of Uceris (budesonide) rectal foam, for the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling for the package insert, patient package insert, instructions for use, and the carton and immediate container labels. This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The listed drug upon which your application relies is subject to a period of patent protection and therefore final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired.

Your application contains certifications to patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application (“Paragraph IV certifications”).

Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of 45 days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the Act.

However, because the 45-day period described in section 505(c)(3)(C) of the Act has not yet expired, final approval cannot be granted.

To obtain final approval of this application, submit an amendment two or six months prior to the: 1.) expiration of the patent(s) or 2.) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, if this application is ultimately approved, you will be exempt from this requirement.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

(b) (4)

The timetable you submitted on September 5, 2014, states that you will conduct this trial according to the following schedule:

Final Protocol Submission: (b) (4)
Trial Completion:
Final Report Submission:

If you have any questions, contact Kelly Richards, Regulatory Project Manager, at (240) 402-4276.

Sincerely,

{See appended electronic signature page}

Andrew E. Mulberg, MD, FAAP, CPI
Deputy Director
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

32 Page(s) of Draft Labeling have been Withheld in Full as B4 (CCI/TS) immediately following this page

---

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ANDREW E MULBERG
09/15/2014