DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022205

NDA APPROVAL

Salix Pharmaceuticals, Inc.
Attention: Benjamin Burgin, RAC
Senior Manager, Regulatory Affairs
8510 Colonnade Center Dr.
Raleigh, NC 27615

Dear Mr. Burgin:

Please refer to your New Drug Application (NDA) dated July 16, 2007, received July 17, 2007, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Giazo (balsalazide disodium) tablets, 1.1 g.

We acknowledge receipt of your submissions dated August 16, 2007, September 21, 2007, November 16, 2007, November 21, 2007, November 30, 2007, December 22, 2007, February 15, 2008, February 20, 2008, March 6, 2008, March 10, 2008, March 20, 2010, March 24, 2008, June 30, 2008, August 19, 2008, September 8, 2008, September 19, 2008, October 28, 2008, November 11, 2008, January 7, 2009, February 3, 2009, April 7, 2009, October 26, 2009, January 21, 2010, February 16, 2010, April 16, 2010, April 21, 2010, April 26, 2010, August 03, 2011, December 07, 2011, and February, 03, 2012.

The August 03, 2011, submission constituted a complete response to our April 27, 2010, action letter.

This new drug application provides for the use of Giazo (balsalazide disodium) tablets, 1.1 g for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels and carton and immediate container labels submitted on April 14, 2010, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 022205**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROPRIETARY NAME

The Division of Medication Error and Prevention Analysis (DMEPA) and the Division of Gastroenterology and Inborn Errors Products do not object to the use of the proprietary name, Giazo, for this product.

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the active ingredient for this drug product for the treatment of pediatric ulcerative colitis has an orphan drug designation, you are exempt from this requirement.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments in your submission dated February 03, 2012. These commitments are listed below.

PMC 1627-1: A single- and repeated-dose pharmacodynamics and pharmacokinetics trial of Giazo tablets administered orally to pediatric patients ages 12 years to less than 17 years with mildly to moderately active ulcerative colitis to support pediatric labeling.

Final Protocol Submission:	06/2013
Trial Completion:	06/2015
Final Report Submission:	12/2015

PMC 1627-2: A placebo-controlled clinical trial in female patients with active ulcerative colitis to assess the efficacy of an eight week course of Giazo therapy for the treatment of active disease in this patient population.

Final Protocol Submission:	01/2013
Trial Completion:	06/2015
Final Report Submission:	12/2015

PMC 1627-3: A pharmacokinetic trial in patients to evaluate the effect of concomitant therapy with antibiotics commonly used in ulcerative colitis on the metabolism of balsalazide following administration of Giazo.

Final Protocol Submission:	01/2013
Trial Completion:	01/2015
Final Report Submission:	06/2015

Submit clinical protocols to your IND 038492 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kevin Bugin, Regulatory Project Manager, at (301) 796-2302.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Division Director
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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

/s/

DONNA J GRIEBEL
02/03/2012