CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-892

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-892

Salix Pharmaceuticals, Inc.
Attention: Jill Kompa, Director, Regulatory Affairs
1700 Perimeter Park Drive
Morrisville, NC 27560

Dear Ms. Kompa:

Please refer to your new drug application (NDA) dated April 29, 2005, received May 17, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for OsmoPrep™ (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP).

We acknowledge receipt of your submissions dated May 10, May 24, June 22, August 4, August 22, September 29, October 7, November 2, November 7, December 12, and December 19, 2005 and February 15, February 22, March 14, and March 15, 2006 .

This NDA provides for the use of 48 grams of OsmoPrep™ (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and the submitted labeling (container label submitted on March 14, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, but no more than 30 days after it is printed. Individually mount 15 copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-892.**" Approval of this submission by the FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and/or new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirements for this application.

We remind you of your postmarketing study commitment in your submission dated March 15, 2006. This commitment is listed below.

Conduct a pharmacokinetic and safety study of OsmoPrep™ in patients with renal impairment.

Protocol Submission:	March 2007
Study Start:	December 2007
Final Report Submission:	December 2008

Submit clinical protocols to your IND for this product. Submit non-clinical and chemistry, manufacturing, and controls protocols and all study 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, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence.**"

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Tanya Clayton, Regulatory Health Project Manager at (301) 796-0871.

Sincerely,

{See appended electronic signature page}
Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Brian Harvey
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