DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-881/S-003

Salix Pharmaceuticals, Inc.
Attention: Gail Glifort
Senior Manager, Regulatory Affairs
1700 Perimeter Park Drive
Morrisville, NC 27560

Dear Ms. Glifort:

Please refer to your supplemental new drug application dated July 31, 2007, received August 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MoviPrep (polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid) Oral solution.

We acknowledge receipt of your submission dated December 6, 2007, received December 7, 2007.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Package Insert (PI), including the addition of "Postmarketing Experience" subsection to the "ADVERSE REACTIONS" section as well as a minor editorial change.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL).

We would like to remind you that all future package insert submissions must be in PLR format as announced in the Federal Register notice dated January 24, 2006 (Volume 71, Number 15).

The final printed labeling (FPL) must be identical to the package insert submitted on July 31, 2007.

Please submit an electronic version of the FPL; 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 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-881/S-003**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Matthew Scherer, Regulatory Project Manager, at (301) 796-2307.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Joyce Korvick

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