DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-097/S-010

Salix Pharmaceuticals, Inc.
Attention: Jill Kompa, M.S., RAC
1700 Perimeter Park Drive
Morrisville, NC 27560

Dear Ms. Kompa:

Please refer to your supplemental new drug application dated September 26, 2005, received September 30, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visicol® (sodium phosphate monobasic monohydrate, USP & sodium phosphate dibasic anhydrous, USP) Tablets.

We acknowledge receipt of your submissions dated December 13, 2005, and March 23 and March 31, 2006.

This "Changes Being Effected" supplemental new drug application provides for additions to the Precautions and Description sections of the package insert and the addition of Post Marketing Reports under the Adverse Reactions section.

We completed our review of this application as amended. This application is approved, effective on the date of this letter, for use in the agreed-upon labeling text. The agreed-upon labeling must be issued at the next printing of the package insert.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and/or submitted labeling (package insert submitted March 31, 2006).

Please submit the final printed labeling (FPL) electronically 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. Please individually mount 15 of the copies on heavy-weight paper or similar material.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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}

Joyce Korvick, M.D., M.P.H.
Deputy 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/

Joyce Korvick

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