DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-610/S-013

Salix Pharmaceuticals, Inc.
Attention: Catherine Maher, Ph.D.
Senior Manager, Regulatory Affairs
1700 Perimeter Drive
Morrisville, NC 27560

Dear Dr. Maher:

Please refer to your supplemental new drug application dated September 13, 2005, received September 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Colazal® (balsalazide disodium) Capsules.

This "Changes Being Effected" supplemental new drug application provides for a new container-closure configuration that is outside of the approved ranges and a new 500 count bottle size.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 13, 2005.

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 Kristen Everett, R.N., Regulatory Project Manager, at (301) 796-0453.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Postmarketing Evaluation
Office of New Drug Quality Assessment
Center of 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/

Hasmukh Patel

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