



NDA 20-610/S-001

Salix Pharmaceuticals, Inc.
Attention: Lorin K. Johnson, Ph.D.
Senior Vice President and Chief Scientific Officer
3600 West Bayshore Road, Suite 205
Palo Alto, CA 94303

Dear Mr. Johnson:

Please refer to your supplemental new drug application dated December 18, 2001, received December 19, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COLAZAL™ (balasalazide disodium) Capsules.

This “Changes Being Effected” supplemental new drug application provides for revisions to the PRECAUTIONS section, Renal subsection of the currently approved package insert based on a Post-Marketing 15-Day Alert report (Mfr. Report #1374).

We acknowledge receipt of your submission dated January 7, 2002.

We have completed the review of this supplemental new drug application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on January 7, 2002. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Practitioner” letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Brian Strongin, R.Ph., M.B.A. at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal & Coagulation Drug
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
6/18/02 01:23:05 PM
for Victor Raczkowski