



NDA 20-610/S-014

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

Dear Ms. Kompa:

Please refer to your supplemental new drug application dated March 22, 2006, received March 23, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Colazal (balsalazide disodium) Capsules, 750 mg.

We acknowledge receipt of your submission dated March 28, 2006.

This supplemental new drug application provides for changes to the approved labeling for Colazal based on food effect data from a postmarketing study and supportive data from previously submitted pharmacokinetic studies.

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 agreed-upon labeling text.

As discussed in the teleconferences on September 15, and September 18, 2006, you agreed to our proposed changes to the package insert, which were faxed to you on September 14, 2006, and September 18, 2006, respectively.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert (PI).

Please submit the approved PI in SPL format according to the guidances for industry titled *Providing Regulatory Submissions in Electronic Format – NDA* and *Providing Regulatory Submissions in Electronic Format – Content of Labeling*. 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

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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, Regulatory Project Manager, at (301) 796-0453.

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 (package insert)

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

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Joyce Korvick  
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