DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-892/S-009
NDA 21-097/S-015

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT
REMS ASSESSMENT ACKNOWLEDGMENT

Salix Pharmaceuticals, Inc.
Attention: Benjamin M. Burgin, RAC
Senior Manager, Regulatory Affairs
1700 Perimeter Park Drive
Morrisville, NC 27560

Dear Mr. Burgin:

Please refer to your Supplemental New Drug Applications (sNDAs) dated August 1, 2011, received August 2, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Osmoprep (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets and Visicol (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets.

These supplemental new drug applications propose to eliminate the requirement for the approved Osmoprep and Visicol REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Osmoprep and Visicol were originally approved on October 13, 2009. Both REMS consist of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

We also refer to your submission dated April 13, 2011, which contained an assessment of the REMS for Osmoprep and Visicol. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

In accordance with Section 505-1(h)(2) of the FDCA, we notified you that we were initiating discussions of your REMS assessment through a teleconference on June 13, 2011. This letter is a follow-up to that teleconference.

You propose that FDA no longer require a REMS for Osmoprep and Visicol.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in

21 CFR 208.1. In addition, we have determined that the communication plan is no longer necessary to ensure that the benefits of the drugs outweigh their risks because key risk information has been communicated to prescribers. Therefore, it is no longer necessary to include the Medication Guide or the communication plan as elements of the approved REMS to ensure that the benefits of Osmoprep and Visicol outweigh their risks.

Therefore, we agree with your proposal and the REMS for Osmoprep and Visicol are no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR part 208.

REPORTING REQUIREMENTS

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.
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Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors 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 A KORVICK
12/09/2011