DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22246/S-005

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT
REMS ASSESSMENT ACKNOWLEDGMENT

Salix Pharmaceuticals, Inc.
Attention: Gail Glifort
Associate Director, Regulatory Affairs
1700 Perimeter Park Drive
Morrisville, NC 27560

Dear Ms. Glifort:

Please refer to your Supplemental New Drug Application (sNDA) dated August 4, 2011, and received August 5, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Metozolv ODT (metoclopramide) orally disintegrating tablets, 5 mg and 10 mg.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment for Metozolv ODT (metoclopramide) dated May 12, 2011.

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 letter dated July 12, 2011. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

This supplemental new drug application proposes to eliminate the requirement for the approved REMS for Metozolv ODT (metoclopramide).

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Metozolv ODT (metoclopramide) was originally approved on September 4, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Metozolv ODT (metoclopramide).

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. Therefore, we agree that it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Metozolv ODT (metoclopramide) outweigh its risks, and a REMS is no longer required for Metozolv ODT (metoclopramide).

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 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 Maureen Dewey, Regulatory Project Manager, at (301) 796-0845.

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

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/s/

JOYCE A KORVICK
08/22/2011