DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022202/S-003/S-004

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Xanodyne Pharmaceuticals, Inc.
One Riverfront Place
Newport, KY 41071-4563

Attention: Carie Masoner
Senior Manager, Regulatory Affairs

Dear Ms. Masoner:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received February 3, and March 14, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zipsor® (diclofenac potassium) Liquid Filled Capsules.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated February 3, 2011, and found it to be adequate.

These supplemental new drug applications propose to eliminate the requirement for the Zipsor Medication Guide-only REMS.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Zipsor (diclofenac potassium) was originally approved on June 16, 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 Zipsor (diclofenac potassium).

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of Zipsor (diclofenac potassium) outweigh its risks. Therefore, we agree with your proposal and a REMS for Zipsor (diclofenac potassium) is no longer required.

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 Sharon Turner-Rinehardt, Senior Regulatory Health Project Manager, at (301) 796-2254 or Katherine Won, Safety Regulatory Project Manager, at (301) 796-7568.

Sincerely,

{See appended electronic signature page}

Laura Governale, Pharm.D., M.B.A.
Acting Deputy Director for Safety
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
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/

KATHERINE S WON
05/04/2011

LAURA A GOVERNALE
05/04/2011