DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-011/S-003

Xanodyne Pharmaceuticals, Inc.
Ove Riverport Place
Newport, KY 41071-4563

Attention: Arthur C. Ilse
Executive Director, Regulatory Affairs

Dear Mr. Ilse:

Please refer to your supplemental new drug application dated January 13, 2009, received January 15, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Roxicodone) Oxycodone Hydrochloride) Tablets, 5 mg, 15 mg, and 30 mg.

We acknowledge receipt of your submissions dated March 26 and April 9, 2009.

This supplemental new drug application provides for the addition of a 5-mg strength tablet.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 26, 2009.

We remind you of your March 8, 2009, agreement to implement the carton and container label changes listed below.

Carton Labels and Container Labels

For all strengths, delete the blue horizontal stripe which separates the trade name and established name/dosage form from the product strength.

Blister Labels

For all strengths, delete the reverse numbering on each blister.

Submit final printed carton and container labels that include the agreed upon changes as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-011/S-003**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Lisa Basham, Regulatory Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Sharon Hertz
5/15/2009 03:37:48 PM
Signing for Bob Rappaport, M.D.