DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-011/S-002

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

Attention: Arthur C. Ilse
Director, Regulatory Affairs

Dear Mr. Ilse:

Please refer to your supplemental new drug application dated August 27, 2008, received August 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Roxicodone® (Oxycodone Hydrochloride Tablets USP).

We also refer to our June 2, 2008, letter in which we requested the inclusion of language in the **PRECAUTIONS: Carcinogenicity, Mutagenesis, and Impairment of Fertility** section of the package insert.

This supplemental new drug application provides for inclusion of the requested language in the **PRECAUTIONS: Carcinogenicity, Mutagenesis, and Impairment of Fertility** section of the package insert.

We have completed our review of this supplemental new drug application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (attached) and with the minor editorial revisions listed below.

1. Under Effects on Gastrointestinal Tract and Other Smooth Muscle, in the first sentence of the second paragraph, insert the word "that" after "…hydrochloric acid in the stomach…".

2. In the statement under **PRECAUTIONS: Carcinogenesis, Mutagenesis, and Impairment of Fertility:** "Oxycodone hydrochloride was genotoxic in an *in vitro* mouse lymphoma assay in the presence of metabolic activation. There was no evidence of genotoxic potential in an *in vitro* bacterial reverse mutation assay (*Salmonella typhimurium* and *Escherichia Coli*) or in an assay for chromosomal aberrations (*in vivo* mouse bone marrow micronucleus assay)." Correct the C in *Escherichia coli* to lowercase.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 21-011/S-002."

LETTERS TO HEALTH CARE PROFESSIONALS

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

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

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Bob Rappaport

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