**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-615/S-002

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

Attention: Authur Ilse
Executive Director, Regulatory Affairs

Dear Mr. Ilse:

Please refer to your supplemental new drug application dated April 6, 2009, received April 7, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duraclon® (clonidine hydrochloride) Injection.

This "Changes Being Effected" supplemental new drug application provides for changes to the **ADVERSE REACTIONS** and **HOW SUPPLIED** sections of the package insert.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling text (FPL) submitted on April 6, 2009.

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 Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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

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/s/

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Sharon Hertz
4/24/2009 12:34:24 PM
Signing for Bob Rappaport, M.D.