DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 17604/S-043

Pedinol Pharmacal Inc.
30 Banfi Plaza North
Farmingdale, NY 11735

Attention: Lance Moore, R.Ph., Esq.
Regulatory Affairs Manager

Dear Mr. Moore:

Please refer to your supplemental new drug application dated December 31, 2008, received January 2, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nalfon® (Fenoprofen Calcium) Capsules.

We acknowledge receipt of your submissions dated February 16, March 15 and 26, and April 30, 2009.

This supplemental new drug application provides for the addition of a new 400 mg strength capsule.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and Medication Guide and the immediate container and carton labels submitted December 31, 2008.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "**FPL for approved supplement NDA 17-604/S-043**." Approval of this submission by FDA is not required before the labeling is used.

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
5800 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sharon Turner-Rinehardt, Regulatory Health Project Manager, at (301) 796-2254.

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

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
7/21/2009 05:48:44 PM
Signing for Bob Rappaport, M.D.