DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-604/S-041

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 April 25, 2007, received April 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nalfon® (fenoprofen calcium).

This "Changes Being Effected" supplemental new drug application provides for revisions to the NSAID Medication Guide table "NSAID medicines that need a prescription" to include the class labeling changes for all NSAID medications and the removal of information pertaining to the 300 mg dose of Nalfon®.

We have completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 25, 2007.

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, please designate this submission "SPL for approved supplement NDA 17-604/S-041."

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Project Manager, at (301) 796-2254.

Sincerely,

{See appended electronic signature page}

Bob 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
8/7/2007 03:26:27 PM
Signing for Bob Rappaport, M.D.