



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-029/S-002

Pharmaceutical Development Group, Inc.
Attention: Cheryl D. Blume, Ph.D.
Authorized Agent for Hisamitsu Pharmaceutical Co., Inc.
13902 North Dale Mabry Highway, Suite 122
Tampa, FL 33618

Dear Dr. Blume:

Please refer to your supplemental new drug application dated February 29, 2008, received March 3, 2008, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Salonpas Pain Relief Patch (10% methyl salicylate & 3% 1-menthol).

We also acknowledge receipt of your submission dated March 18, 2008.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a complementary 3-count sample (package) pouch of Salonpas Pain Relief Patch and Salonpas Arthritis Pain.

We have completed our review of this application, as amended. This application 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 (3-count sample pouch labels) submitted February 29, 2008.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 22-029/S-002.**" 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
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Darrell Lyons, Regulatory Project Manager, at (301) 796-4092.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer
8/25/2008 12:15:02 PM