DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-029/S-003

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 December 19, 2008, received December 22, 2008, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Salonpas Pain Relief Patch (10% methyl salicylate & 3% l-menthol).

This "Changes Being Effected in 30 days" supplemental new drug application proposes to change the "If pregnant or breastfeeding" warning on the Drug Facts label from "If pregnant or breast feeding, ask a doctor before use during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery" to "If pregnant or breast-feeding, ask a doctor before use while breast-feeding and during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery" for both the Salonpas Pain Relief Patch and Salonpas Arthritis Pain labels.

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 (Salonpas Pain Relief Patch 5 and 15-count cartons, 5-count pouch, and 3-count complementary pouch labels; Salonpas Arthritis Pain 5- and 15-count carton, 5-count pouch, and 3-count complementary pouch labels) submitted on December 19, 2008. These must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

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-003**." 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

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

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