DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022029/S-007

SUPPLEMENT APPROVAL

Hisamitsu Pharmaceutical Co., Inc.
U.S. Agent: Pharmaceutical Development Group
Attention: Cheryl D. Blume, Ph.D.
13902 North Dale Mabry Highway, Suite 230
Tampa, FL 33618

Dear Dr. Blume:

Please refer to your Supplemental New Drug Application (sNDA) dated May 17, 2010, received May 18, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Salonpas Pain Relief (10% methyl salicylate and 3% 1-menthol) Patch.

This "Prior Approval" supplemental new drug application proposes the following changes:

- The addition of a sample immediate container (pouch) containing a single Salonpas patch that is not intended for resale.
- A new aluminum laminate immediate container (pouch) system that is different from that employed for both the five-patch and three-patch immediate containers (pouches).

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (Salonpas Pain Relief Patch 1-count immediate container (pouch) label, and Salonpas Arthritis Pain 1-count immediate container (pouch) label submitted May 17, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the Salonpas Pain Relief Patch 1-count and Salonpas Arthritis Pain 1-count cartons, we request that you submit these cartons as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 022029/S-007**." Approval of this submission by FDA is not required before the labeling is used.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Immediate Container Labels

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22029	SUPPL-7	HISAMITSU PHARMACEUTICAL CO INC	SALONPAS POWER PLUS(METHYL SALICYLATE/ME

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
09/13/2010