DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022029/S-011

SUPPLEMENT APPROVAL

Hisamitsu Pharmaceutical Co., Inc.
U.S. Agent: Pharmaceutical Development Group, Inc.
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 January 4, 2012, received January 5, 2012 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Salonpas Pain Relief (methyl salicylate 10% and l-menthol 3%) Patch.

We acknowledge receipt of your amendments dated February 29, May 10, June 8, July 2, August 8, 29, October 5, 9, 15 and 16, 2012.

This "Prior Approval" supplemental new drug application proposes the following changes: a larger (10 cm X 14 cm) Salonpas Pain Relief Patch and a larger (10 cm X 14 cm) Salonpas Arthritis Pain Patch.

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.

LABELING

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 labeling submitted October 15, 2012, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. The following is a list of the labeling submitted on October 15, 2012:

- Outer container 3-count carton "SALONPAS Pain Relief Patch", minty scent
- Outer container 2-count carton "SALONPAS Pain Relief Patch", minty scent
- Immediate container 3-count pouch "SALONPAS Pain Relief Patch", minty scent
- Immediate container 2- count pouch "SALONPAS Pain Relief Patch", minty scent
- Immediate container 1-count pouch "SALONPAS Pain Relief Patch", minty scent
- Immediate container 1-count pouch "SALONPAS Pain Relief Patch"- FREE SAMPLE, minty scent
- "Shelf-box/sleeve" (dispensing tray) for holding 1-count single pouch patch, "SALONPAS Pain Relief Patch ", minty scent
- Outer container 3-count carton "SALONPAS Arthritis Pain Patch", minty scent

- Outer container 2-count carton "SALONPAS Arthritis Pain Patch", minty scent
- Immediate container 3-count pouch "SALONPAS Arthritis Pain Patch", minty scent
- Immediate container 2-count pouch "SALONPAS Arthritis Pain Patch", minty scent
- Immediate container 1-count pouch "SALONPAS Arthritis Pain Patch", minty scent
- Immediate container 1-count pouch "SALONPAS Arthritis Pain Patch"- FREE SAMPLE, minty scent
- "Shelf-box/sleeve" (dispensing tray) for holding 1-count single pouch patch, "SALONPAS Arthritis Pain Patch", minty scent

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 22-029/S-011**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 months to 2 years and 11 months due to safety concerns related to salicylate exposure and Reye's syndrome; we are waiving trials in children aged 3 to 5 years 11 months of age because sprains and strains only very infrequently occur in this age group, therefore the drug does not represent a meaningful therapeutic benefit over existing therapies and is not likely to be used by a substantial number of pediatric patients.

We are deferring submission of pediatric studies for ages 6 years to 17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. The required studies are listed below.

1939-1 You must conduct a single dose pharmacokinetic trial in children 6 years to 17 years.

Final Protocol Submission:	November 2013
Trial Completion:	November 2015
Final Report Submission:	November 2016

1939-2 You must conduct a multiple dose pharmacokinetic trial in children 6 years to 17 years.

Final Protocol Submission:	November 2013
Trial Completion:	November 2015
Final Report Submission:	November 2016

1939-3 You must conduct a safety and efficacy trial in children 6 years to 17 years

Final Protocol Submission:	November 2013
Trial Completion:	November 2015
Final Report Submission:	November 2016

Submit the protocols to your IND 062735, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

POSTMARKETING COMMITMENTS NOT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

1939-4 Include a visible identifying label, when worn, on the backing membrane of the drug product. The label should include the product name and strength (expressed as a percent of formulation). In addition, you will need to:

1) Assess the impact of the identifying label on the stability of the drug product.

2) Assess any interaction of utilized inks with the drug product.

3) Assess the utilized inks for leachables and extractables.

The timetable you submitted on October 16, 2012, states that you will conduct this study according to the following schedule:

Final Report Submission: May 2014

Submit clinical protocols to your IND 062735 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to this postmarketing commitment should be prominently labeled "**Postmarketing Commitment Correspondence**."

REPORTING REQUIREMENTS

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 Jade Pham, Regulatory Project Manager, at (301) 796-7031.

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

ENCLOSURES:
Carton and Container Labeling

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
11/05/2012