DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022029/S-012

SUPPLEMENT APPROVAL
RELEASE FROM POSTMARKETING REQUIRMENT
FULFILLMENT OF POSTMARKETING REQUIREMENT

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 May 30, 2012, received May 31, 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 July 24, 26, August 8, October 9, 2012 and February 27, 2013.

This "Prior Approval" supplemental new drug application proposes to provide the following language in the Directions section of the "Drug Facts":

"Children under 18 years of age: do not use; use in children under 18 has not been established"

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The Directions section of the "Drug Facts" should read as follows:

"Children under 18 years of age: do not use; this product has not been shown to work in children"

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: 5-, 3-, 1- and 1-FREE SAMPLE-count immediate containers (patches), 5- and 3-outer carton labels and the dispensing trays for the 1-count patch pouches submitted on February 27, 2013, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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-012**." 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 indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We remind you of your pediatric study requirements, as described in our February 20, 2008, approval letter:

1073-1 Deferred pediatric study under PREA for the temporary relief of mild to moderate aches and pains of muscles and joints associated with arthritis, simple backache, strains, bruises and sprains in pediatric patients ages 3 to 17.

The pediatric study requirement for ages 0 months to 2 years and 11 months was waived due to safety concerns related to salicylate exposure and Reye's syndrome. Additionally, as stated in our November 5, 2012, supplement approval letter, pediatric studies in children aged 3 to 5 years 11 months of age were waived because sprains and strains only very infrequently occur in this age group, therefore Salonpas 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 have reviewed your submission dated May 30, 2012 and have determined that you have fulfilled the above requirement for study of Salonpas in patients ages 13 to 17 years and 11 months. In addition, based on the lack of efficacy found in the 13-17 year age group, we are waiving the requirement for studies in patients ages 3 years to 12 years and 11 months because there is evidence strongly suggesting that the drug product would be ineffective and/or unsafe in this pediatric group. Therefore, you are released from this portion of the postmarketing requirement.

Because you have fulfilled the requirement for study of Salonpas in one age group and are waived from the remainder, this postmarketing requirement will be administratively separated into two postmarketing requirements as follows:

1073-2 Deferred pediatric study under PREA for the temporary relief of mild to moderate aches and pains of muscles and joints associated with arthritis, simple backache, strains, bruises and sprains in pediatric patients ages 3 to 12 years and 11 months.

This requirement is released.

1073-3 Deferred pediatric study under PREA for the temporary relief of mild to moderate aches and pains of muscles and joints associated with arthritis, simple backache, strains, bruises and sprains in pediatric patients ages 13 to 17 years and 11 months.

This requirement is fulfilled.

We remind you that there are postmarketing requirements and commitments listed in the November 5, 2012, approval letter that are still open.

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
03/29/2013