



NDA 22029/S-014

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 July 31, 2013, received August 1, 2013, submitted under 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.

This “Changes Being Effected” supplemental new drug application proposes to add a new packaging configuration and associated labeling changes for Salonpas Pain Relief Patch: a 6-patch box (containing two 3-patch 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.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the: 6-count carton (containing two 3-patch pouches) and the 3-count immediate container pouches submitted on July 31, 2013, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The FPL 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 22029/S-014.**” 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.

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}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):

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/

THERESA M MICHELE
01/31/2014