NDA 22029/S-019

SUPPLEMENT APPROVAL

Biotech Research Group
Attention: William Spanogle III, PhD
Sr Director Product and Process Development
U.S. Agent for Hisamitsu Pharmaceutical Co., Inc.
3810 Gunn Highway
Tampa, FL 33618

Dear Dr. Spanogle:

Please refer to your supplemental new drug application (sNDA) dated and received July 29, 2021, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Salonpas Pain Relief Patch (10% methyl salicylate and 3% L-menthol) topical patch.

This "Changes Being Effected" supplemental new drug application provides for an update under the "If pregnant or breast-feeding" warning in the Drug Facts labeling in response to the Agency's CBE Supplement Request letter dated April 28, 2021.

APPROVAL & LABELING

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

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 labeling listed in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	**Date Submitted**
Salonpas Pain Relief Patch	
Original size-1ct outer container (pouch) – Sample	July 29, 2021
Original size-1ct outer container (pouch)	July 29, 2021
Original size-3ct outer container (pouch)	July 29, 2021
Original size-3ct immediate container (pouch)	July 29, 2021
Original size-5ct immediate container (pouch)	July 29, 2021
Original size-5ct outer container (carton)	July 29, 2021
Original size-6ct BONUS outer container (carton)	July 29, 2021
Original size-15ct outer container (carton)	July 29, 2021
Original size-20ct outer container (carton)	July 29, 2021
Large size-1ct outer container (pouch) – Sample	July 29, 2021

Large size-1ct immediate container (pouch)	July 29, 2021
Large size-2ct immediate container (pouch)	July 29, 2021
Large size-2ct outer container (carton)	July 29, 2021
Large size-3ct immediate container (pouch)	July 29, 2021
Large size-3ct outer container (carton)	July 29, 2021
Large size-9ct outer container (carton)	July 29, 2021
Salonpas Arthritis Pain Patch	
Original size-1ct outer container (pouch) – Sample	July 29, 2021
Original size-1ct outer container (pouch)	July 29, 2021
Original size-3ct outer container (pouch)	July 29, 2021
Original size-5ct immediate container (pouch)	July 29, 2021
Original size-5ct outer container (carton)	July 29, 2021
Original size-15ct outer container (carton)	July 29, 2021
Large size-1ct outer container (pouch) – Sample	July 29, 2021
Large size-1ct outer container (pouch)	July 29, 2021
Large size-2ct immediate container (pouch)	July 29, 2021
Large size-2ct outer container (carton)	July 29, 2021
Large size-3ct immediate container (pouch)	July 29, 2021
Large size-3ct outer container (carton)	July 29, 2021

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 22029/S-019**." 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 are 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 Helen Lee, Safety Regulatory Project Manager, at 301-796-6848.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

VALERIE S PRATT
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