**COLD SPOT POINT RELIEF - menthol swab**
**Fabrication Enterprises, inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**coldspot point relief**

menthol - usp 12%

aqua (deionized water), arnica montana flower (arnica) extract, chondroitin sulfate, citric acid, eucalyptus globulus oil, glucosamine sulfate,ilex paraguariensis leaf (yerba mate) extract, isopropyl alcohol, menth piperita (pepperment) oil, MSM (dimethyl sulfone) polysorbate-20, SD-alcohol 40B, triethanolamine

Keep out of reach of children. If swallowed, consult physician.

for external use only

avoid contact with eyes

do not apply to open wounds or damaged skin

if symptoms persist for more than seven days, discontinue use and consult physician

keep out of reach of children. if swallowed, consult physician

do not bandage tightly

for temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains and/or sprains.

wipe onto affected area. discard wipe and clean hands after use. do not use more than four times per day.

For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains and/or sprains.

cold spot point relief wipes

PRIME
LABEL AND SCREEN, INCORPORATED
W232 N2685 Roundy Circle, East
Pewaukee, WI 53072
262-542-1600
Fax: 262-542-2950

| | |
|---|---|
| Client: Sonic Packaging Industries, Inc. | PLEASE CHECK YOUR PROOF CAREFULLY! |
| Job #: 23700 Date: 08/30/11 | Please review this proof carefully. Please check names, numbers, spelling, punctuation, layout, size, etc. We are asking that you take the responsibility of final approval before we go to press. Thank you for your assistance! |
| Item: ADN00006FLM | |
| Size: 8" X 2.5" Finished Pouch 4" x 2.5" | |

*Before your order can be printed, this proof must be returned to_____with your signed approval.*

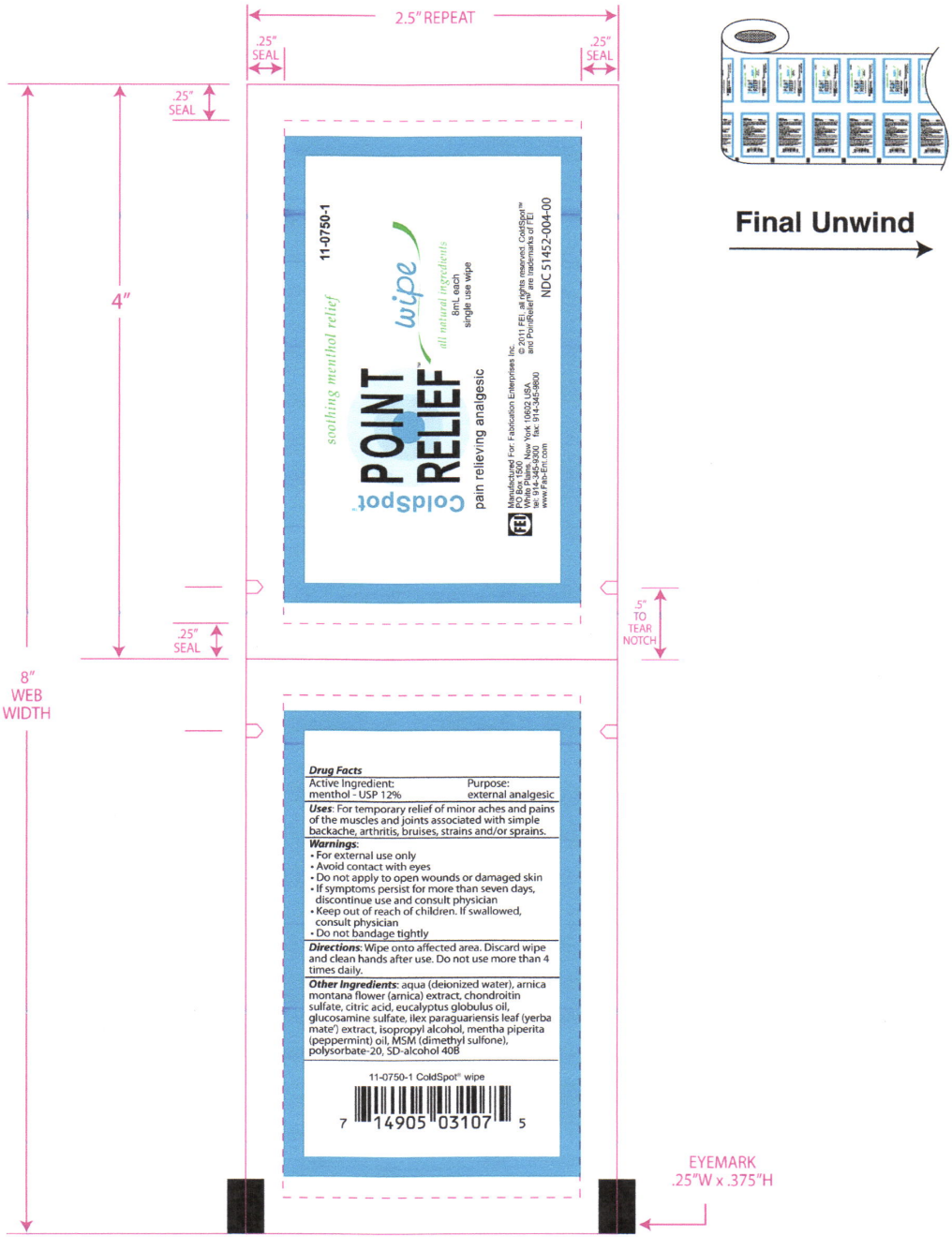
- ☐ *Proof is OK. Print as is.*
- ☐ *Minor correction, OK to print after change.*
- ☐ *Changes needed as indicated, please proof again.*

*Signature:*_____

*Date:*_____ *Job #:*_____

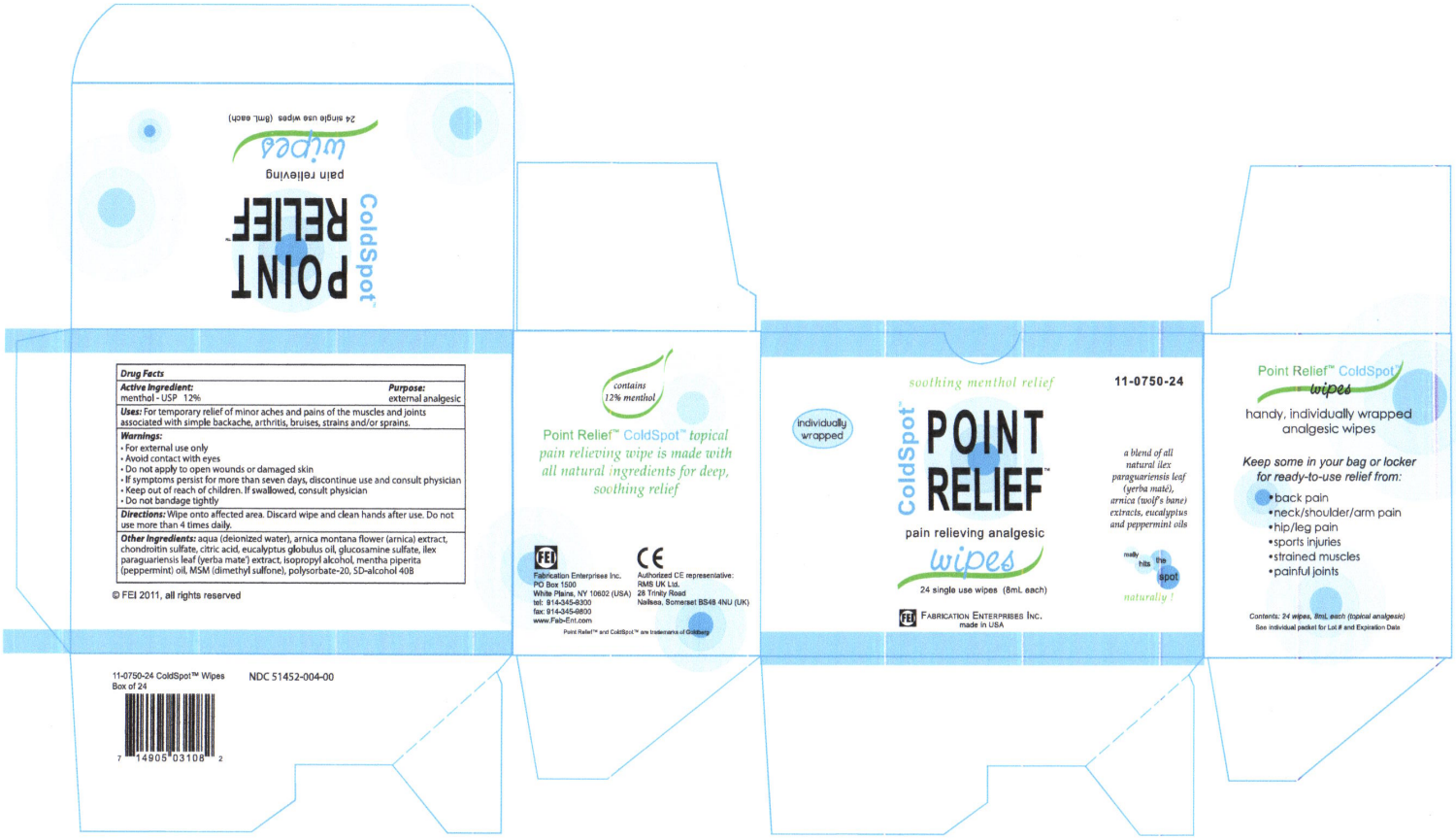
This Proof Indicates Approximate Color Only.
For Accurate Color Match, Use Actual PANTONE Chips.
DO NOT USE COLORS ON THIS FILE AS THEY DO NOT MATCH PMS COLORS.

PMS 361 | PMS 312 | BLACK | DIE LINE DOES NOT PRINT






**Final Unwind**


ColdSpot
POINT RELIEF
pain relieving
wipes
24 single use wipes (8mL each)
Drug Facts
Active Ingredient: menthol - USP 12%
Purpose: external analgesic
Use: For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains and/or sprains.
Warnings:
• For external use only
• Avoid contact with eyes
• Do not apply to open wounds or damaged skin
• If symptoms persist for more than seven days, discontinue use and consult physician
• Keep out of reach of children. If swallowed, consult physician
• Do not bandage tightly
Directions: Wipe onto affected area. Discard wipe and clean hands after use. Do not use more than 4 times daily.
Other Ingredients: aqua (deionized water), arnica montana flower (arnica) extract, chondroitin sulfate, citric acid, eucalyptus globulus oil, glucosamine sulfate, ilex paraguariensis leaf (yerba mate') extract, isopropyl alcohol, mentha piperita (peppermint) oil, MSM (dimethyl sulfone), polysorbate-20, SD-alcohol 40B
© FEI 2011, all rights reserved
11-0750-24 ColdSpot™ Wipes
Box of 24
NDC 51452-004-00
7 14905 03108 2
contains 12% menthol
Point Relief™ ColdSpot™ topical pain relieving wipe is made with all natural ingredients for deep, soothing relief
Fabrication Enterprises Inc.
PO Box 1500
White Plains, NY 10602 (USA)
tel: 914-345-9300
fax: 914-345-9800
www.Fab-Ent.com
Authorized CE representative:
RMS UK Ltd.
28 Trinity Road
Nailsea, Somerset BS48 4NU (UK)
Point Relief™ and ColdSpot™ are trademarks of Goldberg
soothing menthol relief
11-0750-24
individually wrapped
ColdSpot
POINT RELIEF
pain relieving analgesic
wipes
24 single use wipes (8mL each)
Fabrication Enterprises Inc.
made in USA
a blend of all natural ilex paraguariensis leaf (yerba maté), arnica (wolf's bane) extracts, eucalyptus and peppermint oils
really hits the spot
naturally !
Point Relief™ ColdSpot™
wipes
handy, individually wrapped analgesic wipes
Keep some in your bag or locker for ready-to-use relief from:
• back pain
• neck/shoulder/arm pain
• hip/leg pain
• sports injuries
• strained muscles
• painful joints
Contents: 24 wipes, 8mL each (topical analgesic)
See individual packet for Lot # and Expiration Date

# COLD SPOT POINT RELIEF

menthol swab

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:51452-004 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **Menthol** (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A) | Menthol | .96 mL in 8 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **ARNICA MONTANA FLOWER** (UNII: OZ0E5Y15PZ) | |
| **BOSWELLIA SERRATA RESIN OIL** (UNII: 5T1XCE6K8K) | |
| **BROMELAINS** (UNII: U182GP2CF3) | |
| **alcohol** (UNII: 3K9958V90M) | |
| **Eucalyptus Globulus leaf** (UNII: S546YLW6E6) | |
| **ILEX PARAGUARIENSIS LEAF** (UNII: 1Q953B4O4F) | |
| **Peppermint Oil** (UNII: AV092KU4JH) | |
| **Dimethyl Sulfone** (UNII: 9H4PO4Z4FT) | |
| **Chondroitin sulfate (bovine)** (UNII: 6IC1M3OG5Z) | |
| **Citric Acid** (UNII: 2968PHW8QP) | |
| **Isopropyl Alcohol** (UNII: ND2M416302) | |
| **polysorbate 20** (UNII: 7T1F30V5YH) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:51452-004-00 | 8 mL in 1 PACKET | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 10/13/2011 | |

## Labeler - Fabrication Enterprises, inc. (070577218)

## Registrant - Pure Source (969241041)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Pure Source | | 969241041 | manufacture |