HOT SPOT POINT RELIEF- capsaicin gel
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.

Hot Spot Point Relief

acitve ingredients: capsaicin

aqua (deionized water), carbomer, cassia oil, choldroitin sulfate, ethylhexylglycerine, glucosamine sulfate, glycrrhiza glabra (licorice) extract, phenoxyethanol, polysorbate-20

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

external analesic

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

apply directly to affected area. do not use more than four times per day.

HOT SPOT POINT RELIEF

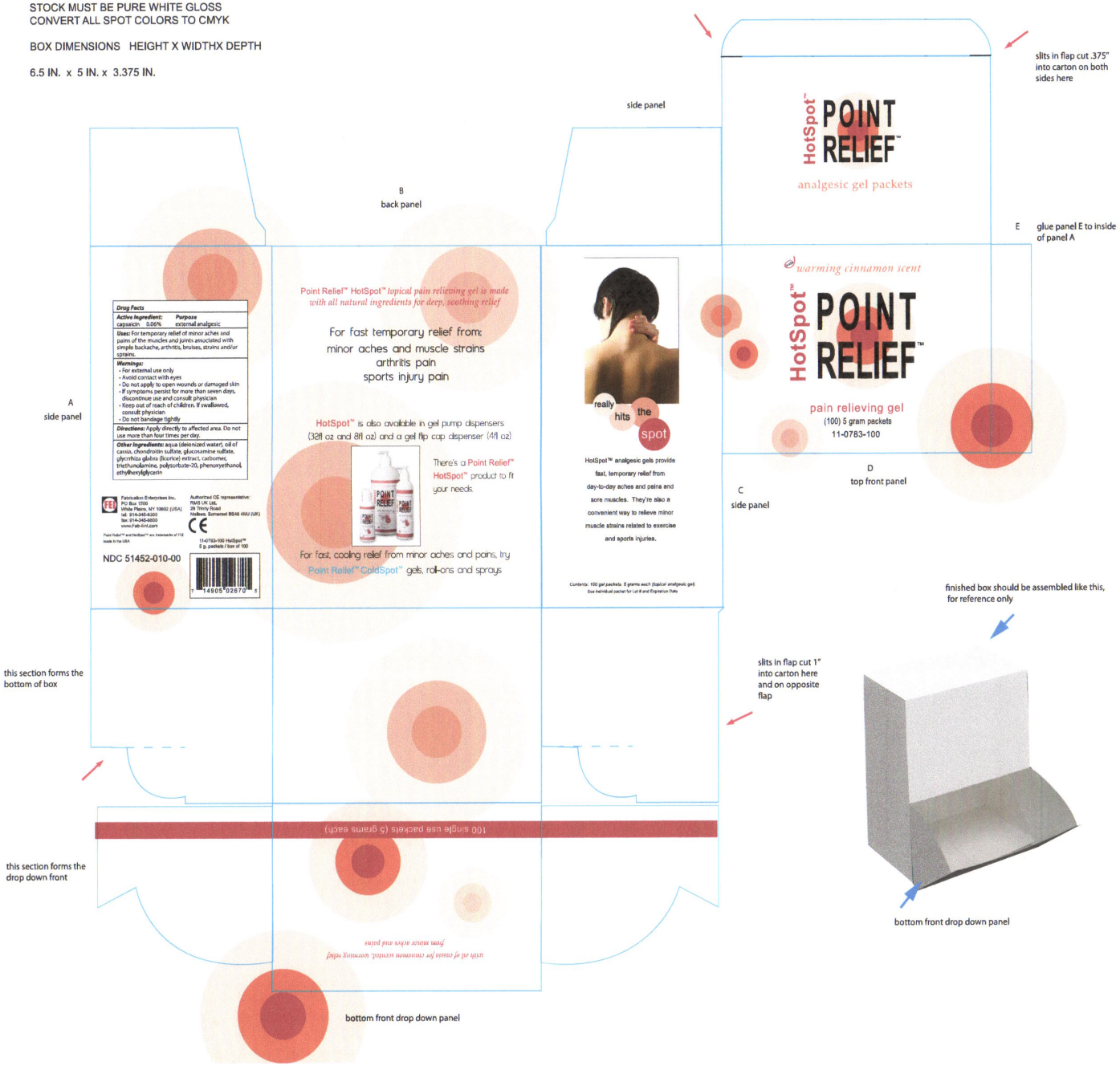
capsaicin gel

DIE LAYER DOES NOT PRINT - FOR GUIDE ONLY

STOCK MUST BE PURE WHITE GLOSS
CONVERT ALL SPOT COLORS TO CMYK

BOX DIMENSIONS HEIGHT X WIDTHX DEPTH

6.5 IN. x 5 IN. x 3.375 IN.



Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51452-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.03 mL in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
polysorbate 20 (UNII: 7T1F30V5YH)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
Glucosamine sulfate (UNII: 1FW7WLR731)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
CARBOMER 1342 (UNII: 809Y72KV36)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CASSIA FISTULA FRUIT (UNII: J65X53KM9E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51452-010-00	5 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/13/2011	

Labeler - Fabrication Enterprises, inc. (070577218)

Registrant - Pure Source (969241041)

Establishment

Name	Address	ID/FEI	Business Operations
pure source		969241041	manufacture

Revised: 10/2011 Fabrication Enterprises, inc.