FAST FREEZE- menthol spray
Natural Essentials 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.

Drug Facts

Active ingredients

Menthol 10%

Purpose

Cooling Pain Relief

Uses

Temporary relief of minor aches and pains of muscles and joints associated with:
- Simple backache
- Arthritis
- Strains
- Sprains

Warnings
- **For external use only**
- Flammable
- Keep away from excessive heat or open flame
- Avoid spraying in eyes
- Contents under pressure. Do not puncture or incinerate container. Do not store at temperature above 120°F (48°C)

Do not use
- With heating pad or device
- With ointments, creams, sprays or liniments
- On wounds, damaged skin or irritated skin

Ask a doctor before use if you
- Have sensitive skin
- Are pregnant or breastfeeding

When using this product
- Avoid contact with eyes or mucous membranes
- Do not bandage tightly

Stop use and ask a doctor if
- Condition worsens
- Symptoms persist for more than 7 days or clear up then reoccur again within a few days
- Irritation develops

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults/Children 2 years and older:
- Spray on the affected area not more than 3 to 4 times daily
- Shake well before use

Children under 2 years old: Consult a physician.

Other information
- Replace cap after use
- Store in a cool, dry place

Inactive ingredients

Aloe Barbadensis (Aloe Vera) Leaf Extract, Ilex Paraguariensis Leaf Extract,SDA-39c Alcohol, Tocopherol (Vitamin E) Acetate, Water

Questions?

Call 317-228-1144 or visit www.Bell-Horn.com or www.fastfreeze.com

Principal Display Panel – Bottle Label

FAST FREEZE®

Naturally
Cool

Pain Relieving

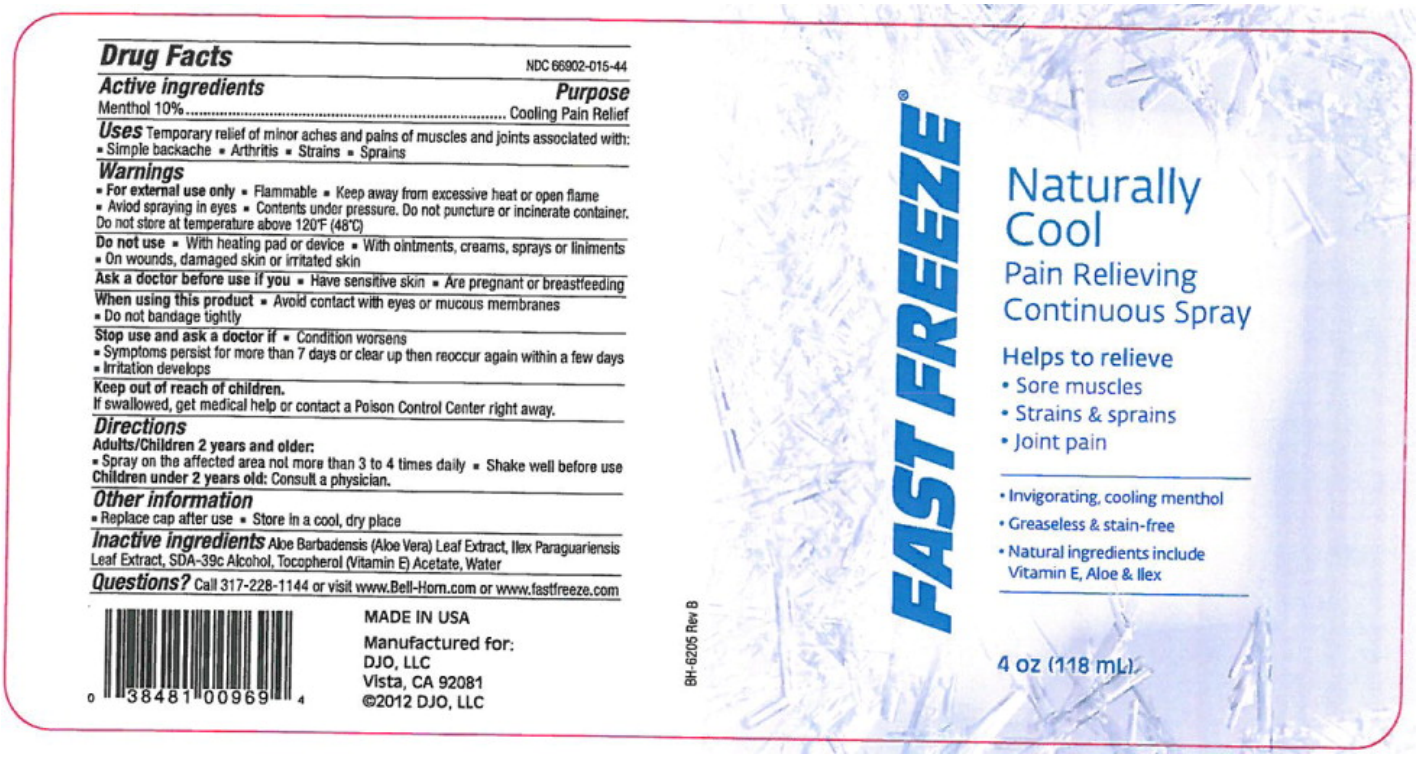
Continuouse Spray

Helps to relieve
- Sore muscles
- Strains & sprains
- Joint pain

…….
- Invigorating cooling menthol
- Greaseless & stain-free
- Natural ingredients include
  Vitamin E, Aloe & llex

…….

4 oz (118 mL)



Drug Facts NDC 66902-015-44

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0 38481 00969 4

MADE IN USA
Manufactured for:
DJO, LLC
Vista, CA 92081
©2012 DJO, LLC

BH-6205 Rev B

FAST FREEZE®

Naturally Cool
Pain Relieving Continuous Spray

Helps to relieve
- Sore muscles
- Strains & sprains
- Joint pain

- Invigorating, cooling menthol
- Greaseless & stain-free
- Natural ingredients include Vitamin E, Aloe & Ilex

4 oz (118 mL)

FAST FREEZE
menthol spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66902-015
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-015-27	1 g in 1 BOTTLE, PUMP		
2	NDC:66902-015-04	1 g in 1 BOTTLE, PUMP		
3	NDC:66902-015-44	1 g in 1 CAN		

4	NDC:66902-015-16	1 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2013	

Labeler - Natural Essentials Inc. (947484713)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Essentials Inc.		947484713	MANUFACTURE(66902-015)

Revised: 12/2012 Natural Essentials Inc.