

**SPRINJENE NATURAL APPLE-MINT- sodium monofluorophosphate paste, dentifrice**  
**SPRINJENE NATURAL WATERMELON- sodium monofluorophosphate paste, dentifrice**  
**Health and Natural Beauty USA Corp**

*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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**SprinJene®**

***Drug Facts***

**Active Ingredient**

Sodium Monofluorophosphate: 0.76% (0.14% w/v fluoride ion)

**Purpose**

Anticavity

**Use**

Helps in the prevention of cavities.

**Warnings**

**Keep out of reach of children under 6 years of age.**

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Supervise children as necessary until capable of using without supervision.

Adults and children 2 years of age and older brush teeth thoroughly, preferably after each meal or at least twice a day as directed by a dentist or physician. Children 2 to 6 years instruct in good brushing and rinsing habits (to minimize swallowing). Children under 2 years do not use unless directed by a dentist or physician.

**Inactive Ingredients**

Aqua, Xylitol, Glycerin, Silica, Calcium Carbonate, Acacia Gum, Corn Zemea (1,3-Propanediol), Vegetable Betaine (Cocamidopropyl Betaine), Flavor, Black Seed Oil (Nigella sativa), Guar Gum, Xanthan Gum, Sodium Bicarbonate, Stevia Rebaudiana Extract, Zinc Citrate, Pectin.

**Questions or comments?**

Call 1-844-346-2872 [www.sprinjene.com](http://www.sprinjene.com)

*Manufactured and Dist. by:*

**Health and Natural Beauty USA Corp.**

**Piscataway, NJ 08854**

**PRINCIPAL DISPLAY PANEL - 99 g Tube Carton - Natural Apple-Mint**

*with Fluoride*

**TOOTHPASTE FOR CHILDREN**

- ☐ **Vegan**
- ☐ **Gluten Free**
- ☐ **Preservative Free**
- ☐ **Dye Free**
- ☐ **Artificial Sweetener Free**
- ☐ **SLS Free**

**SprinJene®**

*Natural*

**APPLE-MINT**

*uses*

*Natural Flavor*

with **Black Seed Oil** (*Nigella sativa*) & **Zinc**  
Birch Tree Xylitol & Acacia Gum

NET WT 3.5 OZ (99 g)

CERTIFIED VEGAN

VEGAN.ORG

**Vegan**

**GLUTEN-FREE**

CERTIFIED

**Gluten Free**

**U**

**Kosher**

HALAL

**Halal**

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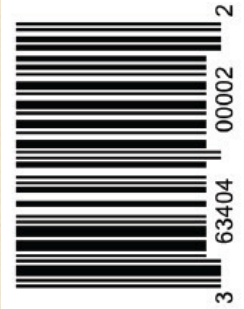
**Drug Facts (continued)**

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MADE IN USA



with Fluoride

TOOTHPASTE FOR CHILDREN

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Natural

APPLE-MINT uses Natural Flavor

with **Black Seed Oil** (*Nigella sativa*) & Zinc  
Birch Tree Xylitol & Acacia Gum



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NET WT 3.5 OZ (99 g)

**SprinJene<sup>®</sup>**  
Natural



SprinJene was developed by a PhD scientist with a long-standing career in oral care products. The SprinJene mission is to create premium oral care products that are uniquely formulated using Science + Nature.

**MAKING THE WORLD SMILE™**

Bursting with the unique benefits of **Black Seed Oil** (*Nigella sativa*) and Zinc

cavity protection • freshens breath • helps dry mouth

- ✓ Vegan
- ✓ Gluten Free
- ✓ Preservative Free
- ✓ Dye Free
- ✓ Artificial Sweetener Free
- ✓ SLS Free

To accommodate the needs of various lifestyles.



with Fluoride

TOOTHPASTE FOR CHILDREN  
**SprinJene<sup>®</sup>**  
Natural

APPLE-MINT uses Natural Flavor



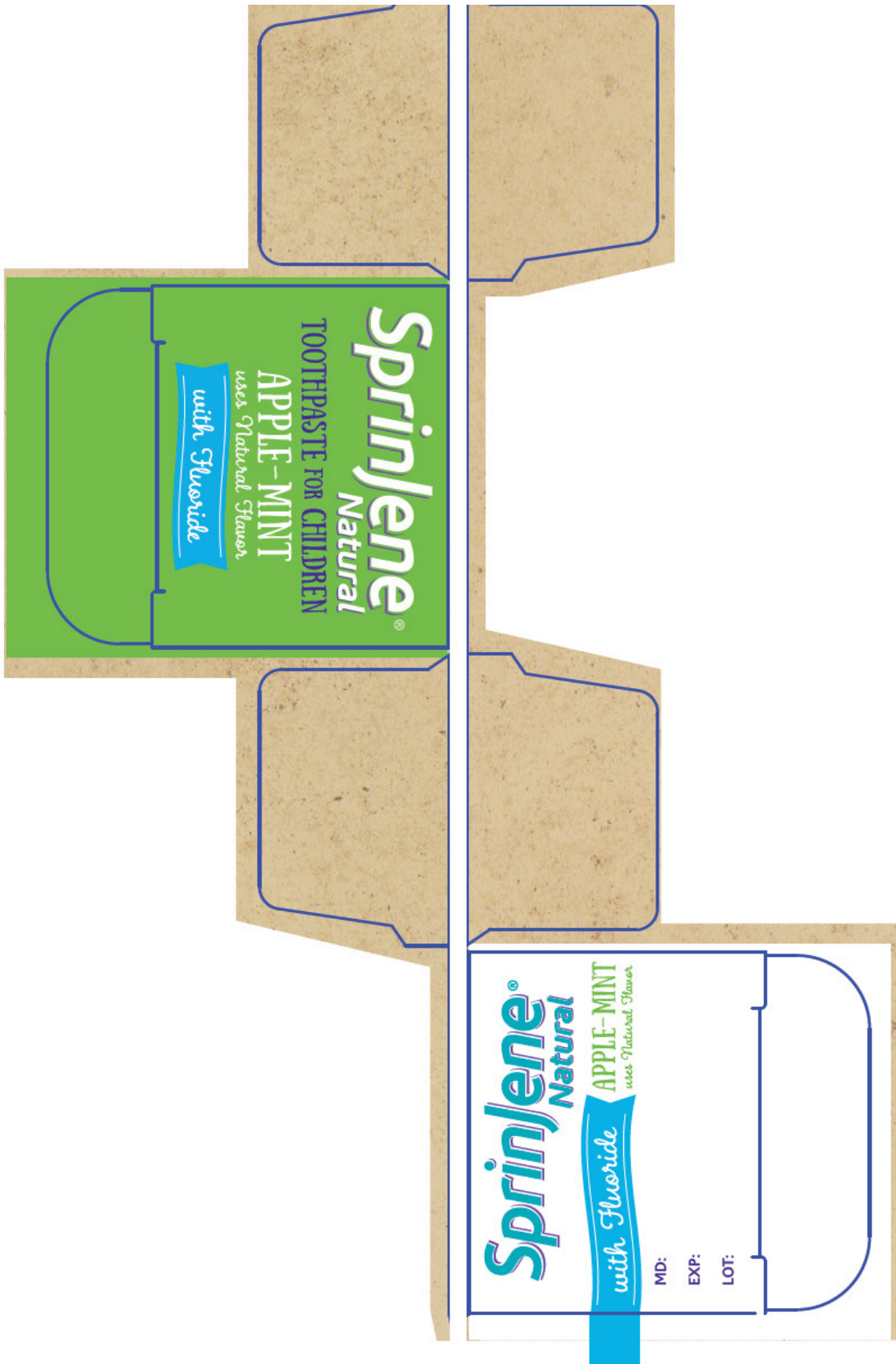
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cavity protection  
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helps dry mouth

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- ✓ Preservative Free
- ✓ Dye Free
- ✓ Artificial Sweetener Free
- ✓ SLS Free







**PRINCIPAL DISPLAY PANEL - 99 g Tube Carton - Natural Watermelon  
with Fluoride  
TOOTHPASTE FOR CHILDREN**

- ☐ **Vegan**
- ☐ **Gluten Free**
- ☐ **Preservative Free**
- ☐ **Dye Free**
- ☐ **Artificial Sweetener Free**
- ☐ **SLS Free**

**SprinJene®**  
**Natural**

**WATERMELON**

*uses*

*Natural Flavor*

with **Black Seed Oil** (*Nigella sativa*) & **Zinc**  
Birch Tree Xylitol & Acacia Gum

NET WT 3.5 OZ (99 g)

CERTIFIED VEGAN  
VEGAN.ORG

**Vegan**

**GLUTEN-FREE**

CERTIFIED  
**Gluten Free**

**U**

**Kosher**

HALAL

**Halal**



## Drug Facts

**Active Ingredient**  
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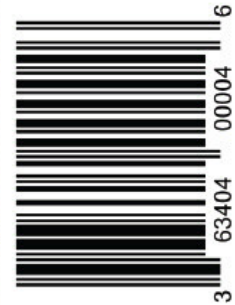
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**Inactive Ingredients** Aqua, Xylitol, Glycerin, Silica, Calcium Carbonate, Acacia Gum, Corn Zemea (1,3-Propanediol), Vegetable Betaine (Cocamidopropyl Betaine), Flavor, Black Seed Oil (Nigella sativa), Guar Gum, Xanthan Gum, Sodium Bicarbonate, Stevia Rebaudiana Extract, Zinc Citrate, Pectin.

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with Fluoride

TOOTHPASTE FOR CHILDREN

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WATERMELON uses Natural Flavor

with Black Seed Oil (*Nigella sativa*) & Zinc  
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## MAKING THE WORLD SMILE™

Bursting with the unique benefits of  
Black Seed Oil (*Nigella sativa*) and Zinc

cavity protection • freshens breath • helps dry mouth

- ✓ Vegan
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To accommodate the needs of various lifestyles.

Certified:

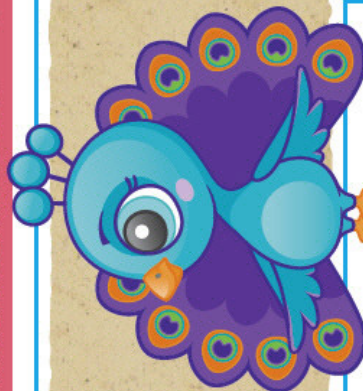


with Fluoride

TOOTHPASTE FOR CHILDREN

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WATERMELON uses Natural Flavor



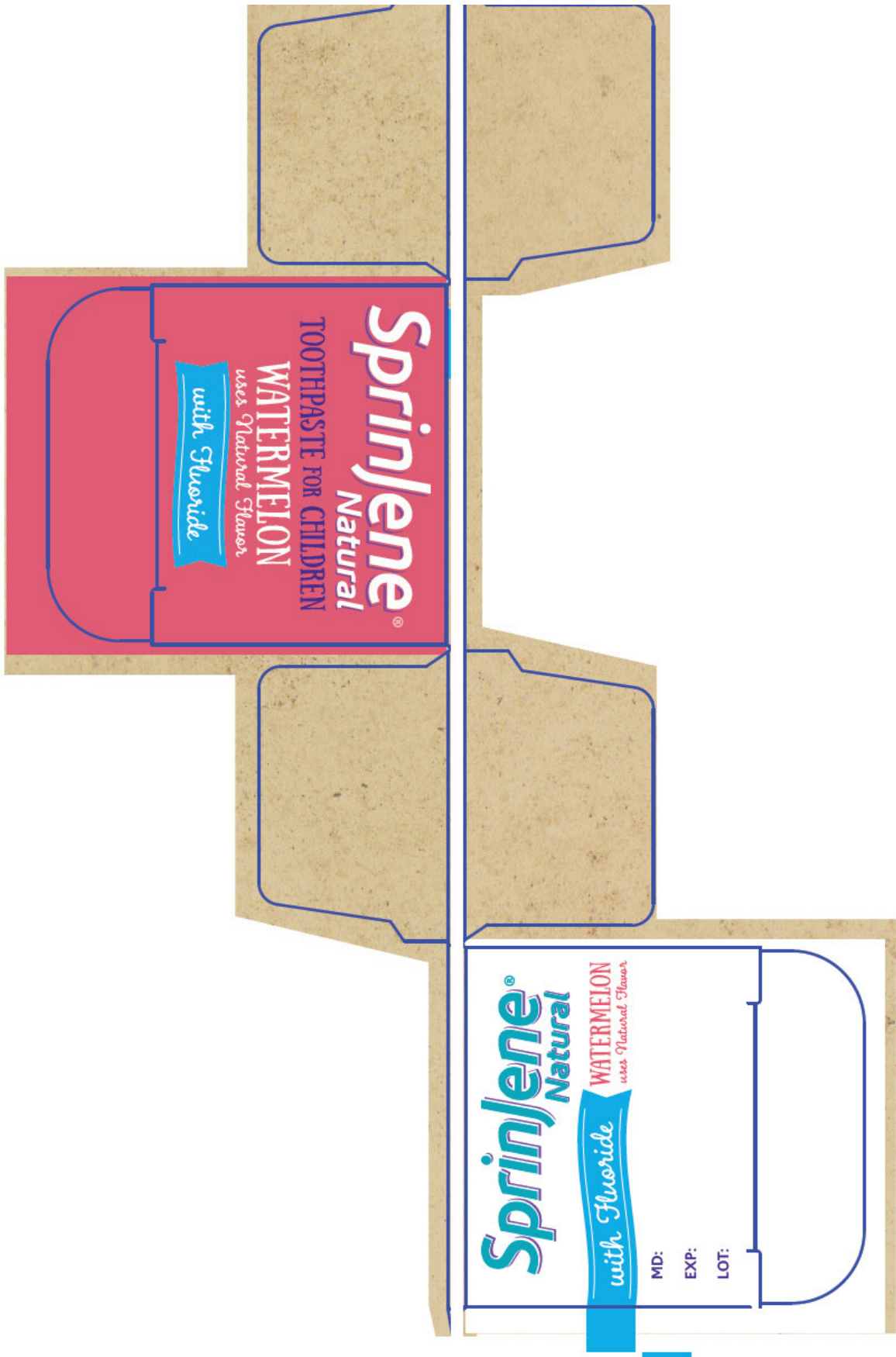
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**SPRINJENE NATURAL APPLE-MINT**  
sodium monofluorophosphate paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63404-2014
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Sodium Monofluorophosphate</b> (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	1.5 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Calcium Carbonate</b> (UNII: H0G9379FGK)	
<b>Acacia</b> (UNII: 5C5403N26O)	
<b>Cocamidopropyl Betaine</b> (UNII: 5OCF3011KX)	
<b>Guar Gum</b> (UNII: E89I1637KE)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Sodium Bicarbonate</b> (UNII: 8MDF5V39QO)	
<b>Zinc Citrate</b> (UNII: K72I3DEX9B)	
<b>Pectin</b> (UNII: 89NA02M4RX)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	WATERMELON	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63404-2014-1	1 in 1 CARTON	02/01/2017	
1		99 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	02/01/2017	

**SPRINJENE NATURAL WATERMELON**

sodium monofluorophosphate paste, dentifrice



**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63404-1203
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Sodium Monofluorophosphate</b> (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	1.5 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Calcium Carbonate</b> (UNII: H0G9379FGK)	
<b>Acacia</b> (UNII: 5C5403N26O)	
<b>Cocamidopropyl Betaine</b> (UNII: 5OCF3011KX)	
<b>Guar Gum</b> (UNII: E89I1637KE)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Sodium Bicarbonate</b> (UNII: 8MDF5V39QO)	
<b>Zinc Citrate</b> (UNII: K72I3DEX9B)	
<b>Pectin</b> (UNII: 89NA02M4RX)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
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OTC MONOGRAPH FINAL	part355	02/01/2017	

**Labeler** - Health and Natural Beauty USA Corp (079129688)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Health and Natural Beauty USA Corp		079129688	MANUFACTURE(63404-2014, 63404-1203)

Revised: 1/2017

Health and Natural Beauty USA Corp