NEUROCOMFORT PAIN RELIEF- neurocomfort lotion NEUROCOMFORT PAIN RELIEF ROLL-ON- neuro comfort roll-on gel NEUROCOMFORT PAIN RELIEF GEL EXTRA STRENGTH- neuro comfort gel extra strength gel

NEUROCOMFORT PAIN RELIEF GEL- neuro comfort gel gel NEUROCOMFORT PAIN RELIEF ROLL-ON EXTRA STRENGTH- neuro comfort roll-on extra strength gel

Harmony Products LLC

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.

NeuroComfort Line

For NDC 73096-021 NeuroComfort Pain Relief



Active ingredient Lidocaine 2%

Inactive ingredients Arnica Montana Flower Extract, Capsaicin, Dimethicone, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hemp Extract, Hempseed Oil, Phenoxyethanol, Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7, Symphytum Officinale (Comfrey) Leaf Extract, Water

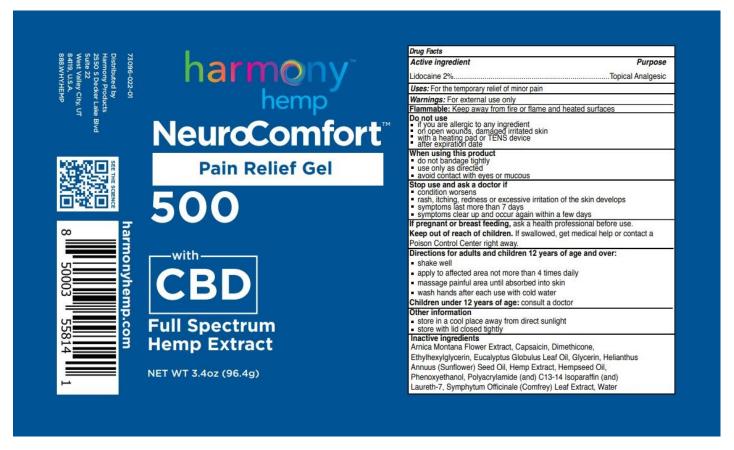
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if -condition worsens -rash, itching, redness or excessive irritation of the skin develops -symptoms last more than 7 days -symptoms clear up and occur again within a few days

Uses: For the temporary relief of minor pain

Purpose Lidocaine 2%......Topical Analgesic

Directions for adults and children 12 years of age and over: -shake well -apply to affected area not more than 4 times daily -massage painful area until absorbed into skin -wash hands after each use with cold water



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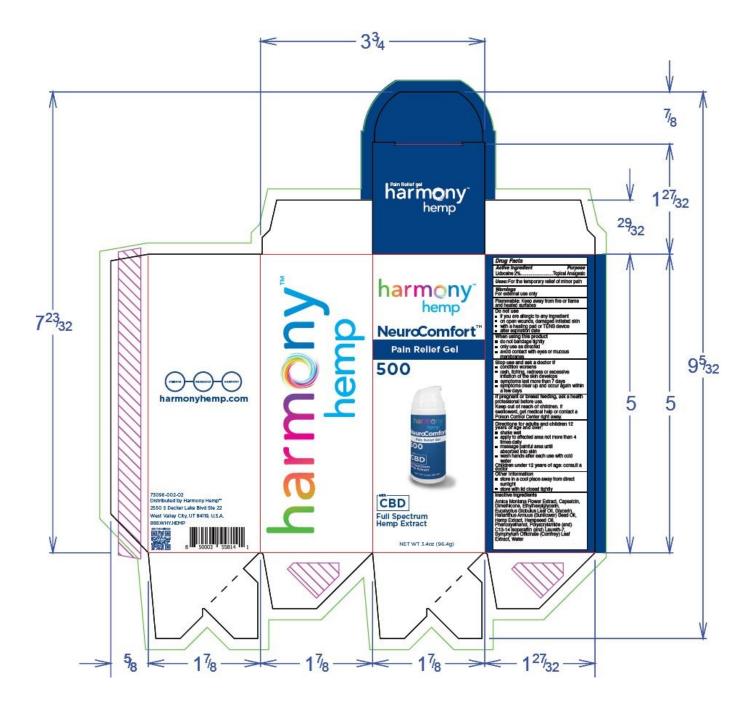
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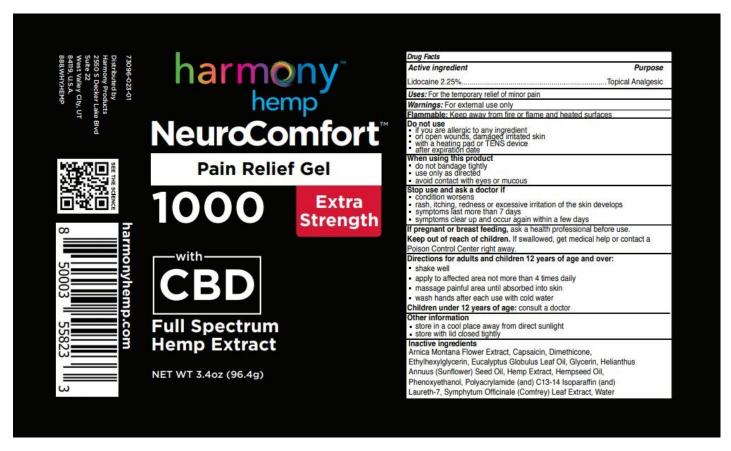
Uses: For the temporary relief of minor pain

Purpose Lidocaine 2%......Topical Analgesic

Directions for adults and children 12 years of age and over: -shake well -apply to affected area not more than 4 times daily -massage painful area until absorbed into skin -wash hands after each use with cold water



For NDC 73096-023 Neuro Comfort Pain Relif Gel Extra Strength



Active ingredient Lidocaine 2.25%

Inactive ingredients Arnica Montana Flower Extract, Capsaicin, Dimethicone, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hemp Extract, Hempseed Oil, Phenoxyethanol, Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7, Symphytum Officinale (Comfrey) Leaf Extract, Water

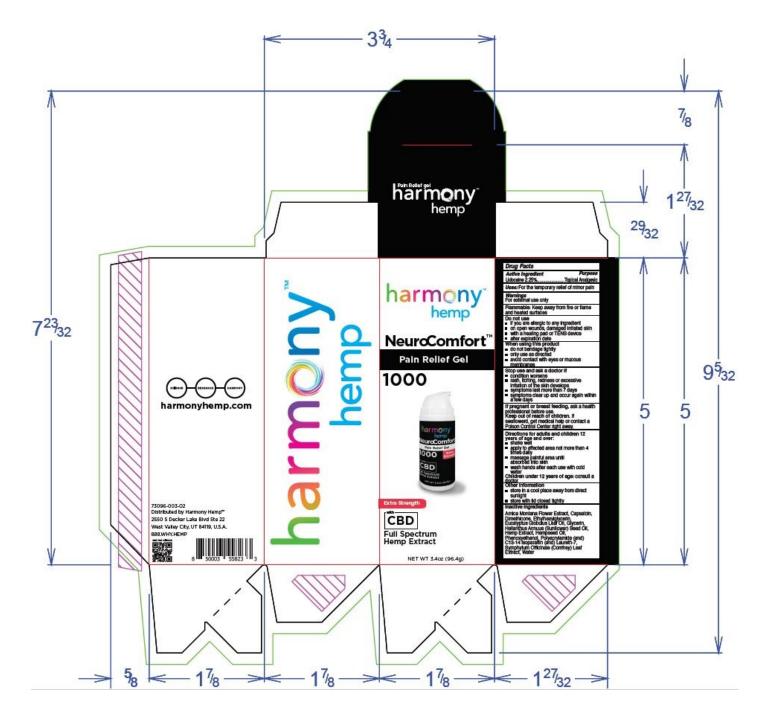
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Uses: For the temporary relief of minor pain

Purpose Lidocaine 2.25%......Topical Analgesic

Directions for adults and children 12 years of age and over: -shake well -apply to affected area not more than 4 times daily -massage painful area until absorbed into skin -wash hands after each use with cold water



For NDC 73096-024 NeuroComfort Pain Relief Roll-on



Active ingredient Lidocaine 2%

Inactive ingredients Arnica Montana Flower Extract, Capsaicin, Dimethicone, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hemp Extract, Hempseed Oil, Phenoxyethanol, Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7, Symphytum Officinale (Comfrey) Leaf Extract, Water

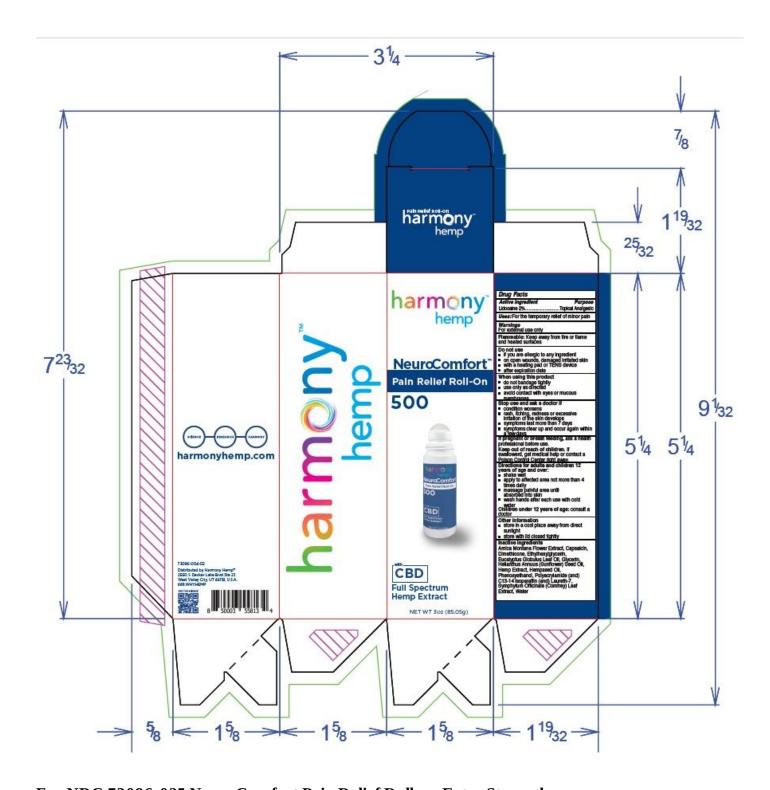
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if -condition worsens -rash, itching, redness or excessive irritation of the skin develops -symptoms last more than 7 days -symptoms clear up and occur again within a few days

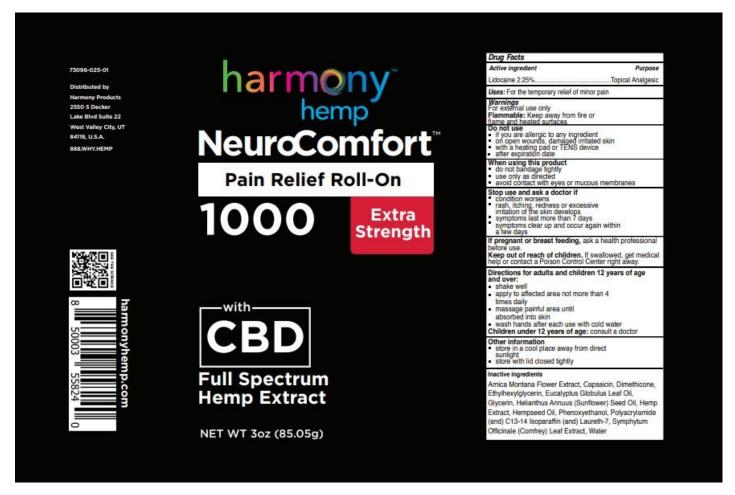
Uses: For the temporary relief of minor pain

Purpose Lidocaine 2%......Topical Analgesic

Directions for adults and children 12 years of age and over: -shake well -apply to affected area not more than 4 times daily -massage painful area until absorbed into skin -wash hands after each use with cold water



For NDC 73096-025 Neuro Comfort Pain Relief Roll-on Extra Strength



Active ingredient Lidocaine 2.25%

Inactive ingredients Arnica Montana Flower Extract, Capsaicin, Dimethicone, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hemp Extract, Hempseed Oil, Phenoxyethanol, Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7, Symphytum Officinale (Comfrey) Leaf Extract, Water

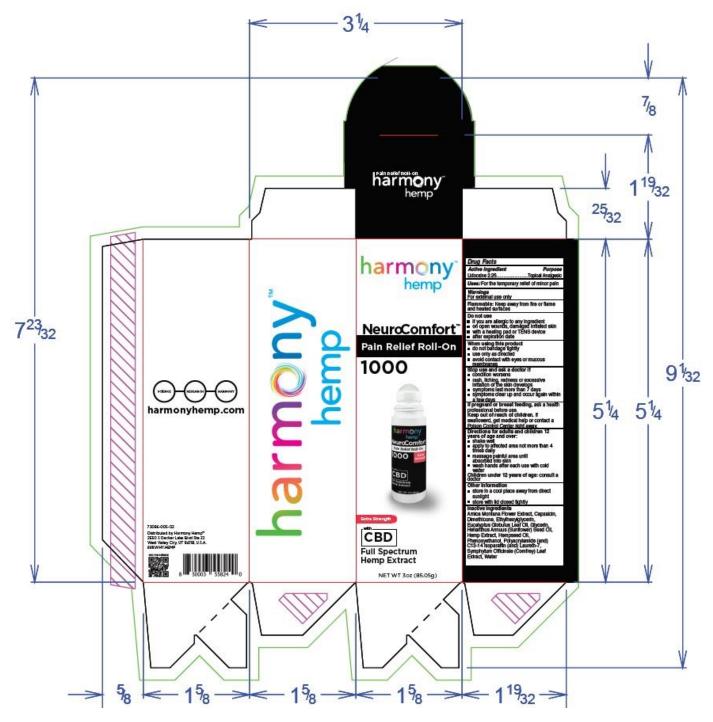
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if -condition worsens -rash, itching, redness or excessive irritation of the skin develops -symptoms last more than 7 days -symptoms clear up and occur again within a few days

Uses: For the temporary relief of minor pain

Purpose Lidocaine 2.25%......Topical Analgesic

Directions for adults and children 12 years of age and over: -shake well -apply to affected area not more than 4 times daily -massage painful area until absorbed into skin -wash hands after each use with cold water



NEUROCOMFORT PAIN RELIEF neurocomfort lotion					
Product Information					
Product Type	Product Type HUMAN OTC DRUG Item Code (Source) NDC:73096-021				
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingred	ient Name		Basis of Strength	Strength	

Inactive Ingredients				
Ingredient Name	Strength			
SUNFLOWER OIL (UNII: 3W1JG795YI)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
CANNABIS SATIVA SEED OIL (UNII: 69 VJ1LPN1S)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
COMFREY LEAF (UNII: DG4F8T839X)				
DIMETHICO NE 1000 (UNII: MCU2324216)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
CAPSAICIN (UNII: S07O44R1ZM)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
HEMP (UNII: TD1MUT01Q7)	500 mg in 226.7 g			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:73096-021- 01	226.7 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/10/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/10/2019	

NEUROCOMFORT PAIN RELIEF ROLL-ON

neuro comfort roll-on gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73096-024	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	1701 mg in 85.05 g	

Inactive Ingredients	
Ingredient Name	Strength

SUNFLOWER OIL (UNII: 3W1JG795YI)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CANNABIS SATIVA SEED OIL (UNII: 69 VJ1LPN1S)	
COMFREY LEAF (UNII: DG4F8T839X)	
DIMETHICO NE 1000 (UNII: MCU2324216)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CAPSAICIN (UNII: S07O44R1ZM)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
HEMP (UNII: TD1MUT01Q7)	500 mg in 85.05 g
EUCALYPTUS OIL (UNII: 2R04ONI662)	

	Packaging			
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:73096- 024-02	1 in 1 CARTON	07/10/2019	
	NDC:73096- 024-01	85.05 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/10/2019	

NEUROCOMFORT PAIN RELIEF GEL EXTRA STRENGTH

neuro comfort gel extra strength gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73096-023	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	2169 mg in 96.4 g	

Inactive Ingredients			
Ingredient Name	Strength		
SUNFLOWER OIL (UNII: 3W1JG795YI)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
CANNABIS SATIVA SEED OIL (UNII: 69 VJ1LPN1S)			

COMFREY LEAF (UNII: DG4F8T839X)	
DIMETHICO NE 1000 (UNII: MCU2324216)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CAPSAICIN (UNII: S07O44R1ZM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
HEMP (UNII: TD1MUT01Q7)	1000 mg in 96.4 g
EUCALYPTUS OIL (UNII: 2R040NI662)	

]	Packaging				
‡	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73096-023- 02	1 in 1 CARTON	07/10/2019		
1	NDC:73096-023- 01	96.4 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Da				
OTC monograph not final	part348	07/10/2019		

NEUROCOMFORT PAIN RELIEF GEL

neuro comfort gel gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73096-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name Basis of Strength Strength				
LIDO CAINE (UNII: 98 PI20 0 987) (LIDO CAINE - UNII: 98 PI20 0 987)	LIDOCAINE	1928 mg in 96.4 g		

Inactive Ingredients				
Ingredient Name	Strength			
SUNFLOWER OIL (UNII: 3W1JG795YI)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
WATER (UNII: 059QF0KO0R)				
CANNABIS SATIVA SEED OIL (UNII: 69 VJ1LPN1S)				
COMFREY LEAF (UNII: DG4F8T839X)				
DIMETHICO NE 1000 (UNII: MCU2324216)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				

ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CAPSAICIN (UNII: S07O44R1ZM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
HEMP (UNII: TD1MUT01Q7)	500 mg in 96.4 g
EUCAL YPTUS O IL (UNII: 2R040Ni662)	

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73096-022- 02	1 in 1 CARTON	07/10/2019		
1	NDC:73096-022- 01	96.4 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	07/10/2019		

NEUROCOMFORT PAIN RELIEF ROLL-ON EXTRA STRENGTH

neuro comfort roll-on extra strength gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73096-025	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name Basis of Strength Strength			
LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	19 14 mg in 85.05 g	

Inactive Ingredients				
Ingredient Name	Strength			
SUNFLOWER OIL (UNII: 3W1JG795YI)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
CANNABIS SATIVA SEED OIL (UNII: 69 VJ1LPN1S)				
COMFREY LEAF (UNII: DG4F8T839X)				
DIMETHICO NE 1000 (UNII: MCU2324216)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
CAPSAICIN (UNII: S07O44R1ZM)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				

HEMP (UNII: TD1MUT01Q7)	1000 mg in 85.05 g		
EUCALYPTUS OIL (UNII: 2R04ONI662)			

Packaging						
# Item	Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:730 025-02	96-	1 in 1 CARTON	07/10/2019			
1 NDC:730 025-01		85.04 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	07/10/2019			

Labeler - Harmony Products LLC (117041828)

Registrant - Steuart Custom Manufacturing (116952121)

Establishment			
Name	Address	ID/FEI	Business Operations
Steuart Custom Manufacturing		116952121	manufacture(73096-021, 73096-022, 73096-023, 73096-024, 73096-025)

Revised: 10/2019 Harmony Products LLC