

**NU-DERM STARTER SET NORMAL-DRY SKIN TRANSFORMATION SYSTEM-
hydroquinone, octinoxate, oxybenzone and zinc oxide
OMP, INC.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

**Obagi Nu-Derm Clear
(Hydroquinone USP, 4%)
Skin Bleaching Cream**

**Obagi Nu-Derm Blender®
(Hydroquinone USP, 4%)
Skin Bleaching Cream**

**Obagi Nu-Derm Sunfader®
(Hydroquinone USP, 4%, Octinoxate USP, 7.5% and Oxybenzone USP, 5.5%)
Skin Bleaching Cream with Sunscreens**

**Rx Only
FOR EXTERNAL USE ONLY**

DESCRIPTION

Hydroquinone is 1,4-benzenediol. Hydroquinone occurs as fine, white needles. The drug is freely soluble in water and in alcohol. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is $C_6H_6O_2$; molecular weight is 110.0.



Each gram of **Obagi Nu-Derm Blender** contains Hydroquinone USP 40 mg/gm in a base of purified water, glycerin, cetyl alcohol, PPG-2 myristyl ether propionate, sodium lauryl sulfate, TEA-salicylate, lactic acid, phenyl trimethicone, tocopheryl acetate, sodium metabisulfite, ascorbic acid, methylparaben, saponins, disodium EDTA, BHT, and propylparaben.

Each gram of **Obagi Nu-Derm Clear** contains Hydroquinone USP 40 mg/gm in a base of purified water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, tocopheryl acetate, ascorbic acid, sodium metabisulfite, lactic acid, saponins, disodium EDTA, methylparaben, BHT, propylparaben, and butylparaben.

Each gram of **Obagi Nu-Derm Sunfader** contains Hydroquinone USP 40 mg/gm, Octinoxate USP, 7.5%, and Oxybenzone USP, 5.5%, in a base of purified water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, tocopheryl acetate, ascorbic acid, sodium metabisulfite, disodium EDTA, methylparaben, saponins, propylparaben, BHT, and butylparaben.

CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3, 4-dihydroxyphenylalanine (dopa) and suppression of other melanocyte metabolic processes.

Exposure to sunlight or ultraviolet light will cause repigmentation of the bleached areas, which may be prevented by the use of sunblocking agents or sunscreen agents contained in Obagi Nu-Derm Sunfader.

INDICATIONS AND USAGE

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation. Obagi Nu-Derm Sunfader is intended for daytime use as it contains sunscreen agents.

CONTRAINDICATIONS

Prior history of sensitivity or allergic reaction to this product or any of its ingredients. The safety of topical hydroquinone use during pregnancy or in children (12 years and under) has not been established.

WARNINGS

Caution

Hydroquinone is a skin bleaching agent which may produce unwanted cosmetic effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this medication.

Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin and check in 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, further treatment is not advised. Close patient supervision is recommended.

Avoid contact with eyes. In case of accidental contact, patient should rinse eyes thoroughly with water and contact physician. A bitter taste and anesthetic effect may occur if applied to lips.

Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity. Obagi Sunfader is formulated for use as a skin bleaching agent and should not be used for the prevention of sunburn.

Warning

Contains sodium metabisulfite, a sulfite that may cause serious allergic type reactions (e.g., hives, itching, wheezing, anaphylaxis, severe asthma attacks) in certain susceptible persons.

PRECAUTIONS

(SEE WARNINGS)

General

Treatment should be limited to relatively small areas of the body at one time since some patients experience a transient skin reddening and a mild burning sensation which does not preclude treatment.

Pregnancy Category C

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether hydroquinone can cause fetal harm when used topically on a pregnant woman or affect

reproductive capacity. It is not known to what degree, if any, topical hydroquinone is absorbed systemically. Topical hydroquinone should be used on pregnant women only when clearly indicated.

Nursing mothers

It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when topical hydroquinone is used by a nursing mother.

Pediatric usage

Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS

No systemic adverse reactions have been reported. Occasional hypersensitivity (localized contact dermatitis) may occur, in which case the medication should be discontinued and the physician notified immediately.

DOSAGE AND ADMINISTRATION

A thin application should be applied to the affected area twice daily or as directed by a physician. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent repigmentation.

HOW SUPPLIED

Obagi Nu-Derm Blender is available as follows:

2 oz. (57 gm) bottle	NDC 62032-100-36
1 oz. (28.5 gm) bottle	NDC 62032-100-10

Obagi Nu-Derm Clear is available as follows:

2 oz. (57 gm) bottle	NDC 62032-101-36
1 oz. (28.5 gm) bottle	NDC 62032-101-10

Obagi Nu-Derm Sunfader is available as:

2 oz. (57 gm) bottle	NDC 62032-116-36
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Store at 25°C (77°F); excursion permitted to 15°C-30°C (59°F-86°F).

OMP, Inc.
Long Beach, CA 90802
USA
1-800-636-7546

Rev. 8/03

PRINCIPAL DISPLAY PANEL - Kit Carton

**OBAGI®
SYSTEM**

NU-DERM®

skin transformation system

starter set

normal/dry

skin transformation system

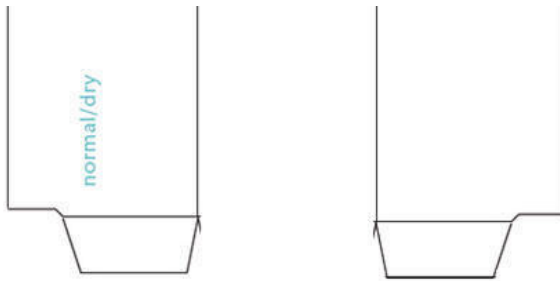


skin transformation system

starter set
normal/dry

This Obagi Nu-Derm® Skin Transformation System Includes:





NU-DERM STARTER SET NORMAL-DRY SKIN TRANSFORMATION SYSTEM

hydroquinone, octinoxate, oxybenzone and zinc oxide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-504
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-504-00	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	57 g
Part 2	1 BOTTLE, PLASTIC	57 g
Part 3	1 BOTTLE, PLASTIC	30 mL
Part 4	1 BOTTLE, PLASTIC	200 mL
Part 5	1 BOTTLE, PLASTIC	200 mL
Part 6	1 BOTTLE, PLASTIC	57 g
Part 7	1 BOTTLE, PLASTIC	57 g

Part 1 of 7

NU-DERM BLENDER SKIN LIGHTENER AND BLENDING

hydroquinone cream

Product Information

Item Code (Source) NDC:62032-100

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 g
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Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0K00R)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC10H)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-100-36	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/1988	

Part 2 of 7

NU-DERM CLEAR SKIN BLEACHING AND CORRECTOR

hydroquinone cream

Product Information

Item Code (Source)	NDC:62032-101
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0K00R)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-101-36	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/1988	

Part 3 of 7

NU-DERM HEALTHY SKIN PROTECTION SPF 35

octinoxate and zinc oxide cream

Product Information

Item Code (Source)	NDC:62032-200
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	90 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LAURETH-7 (UNII: Z95S6G8201)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-200-10	30 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/01/2002	

Part 4 of 7

NU-DERM GENTLE CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) liquid

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	GLYCERETH-7 (UNII: 3D2Y91QZ2H)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	APRICOT KERNEL OIL (UNII: 54JB35T06A)	
INGR	CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		200 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/1988	

Part 5 of 7

NU-DERM TONER

face and neck (excluding shaving preparations) liquid

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
INGR	POTASSIUM ALUM (UNII: 1L24V9R23S)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		200 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/1988	

Part 6 of 7

NU-DERM EXFODERM

face and neck (excluding shaving preparations) lotion

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	CANOLA OIL (UNII: 331KBJ17RK)	
INGR	ISOHEXADECANE (UNII: 918X10UF1E)	
INGR	MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	FYTIC ACID (UNII: 7IGF0S7R8I)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	PEG-150 STEARATE (UNII: 7BSG7DF10Q)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	GLYCERETH-7 (UNII: 3D2Y91QZ2H)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	

Product Characteristics

Color	WHITE	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		57 g in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/1988	

Part 7 of 7

NU-DERM SUNFADER SKIN LIGHTENER WITH SUNSCREEN (SPF 15) PABA FREE
hydroquinone, octinoxate, and oxybenzone lotion

Product Information	
Item Code (Source)	NDC:62032-116
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	55 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-116-36	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/20/2007	

Labeler - OMP, INC. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-504) , LABEL(62032-504) , PACK(62032-504)

Establishment

Name	Address	ID/FEI	Business Operations
Ei INC.		105803274	MANUFACTURE(62032-504) , LABEL(62032-504) , PACK(62032-504) , ANALYSIS(62032-504)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American Products		611921669	MANUFACTURE(62032-504)

Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-504) , REPACK(62032-504)