

KOLORZ SIXTY SECOND FLUORIDE FOAM BLUE RASPBERRY- sodium fluoride aerosol, foam

KOLORZ SIXTY SECOND FLUORIDE FOAM CHERRY CHEESECAKE- sodium fluoride aerosol, foam

KOLORZ SIXTY SECOND FLUORIDE FOAM COTTON CANDY- sodium fluoride aerosol, foam

KOLORZ SIXTY SECOND FLUORIDE FOAM TRIPLE MINT- sodium fluoride aerosol, foam

DMG AMERICA, LLC

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](#).

kolorz® Sixty Second Fluoride Foam

INDICATIONS

For the topical application of fluoride to aid in the protection against dental caries.

Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. See package insert for dosage information.



CONTAINS

Sodium Fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% Fluoride Ion is available from 2.72% Sodium Fluoride. Does not contain chlorofluorocarbon propellant.

Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

WARNING

Avoid spraying toward open flame. Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80° F. Keep from freezing.

EMERGENCY RESPONSE

Call Infotrac 1-800-535-5053

Made in USA

Distributed by: DMG America LLC.

242 South Dean Street

Englewood, NJ 07631

800-662-6383

www.dmg-america.com

Rev. 4/13

RE-ORDER #766202

kolorz®

**By DMG America
Instructions For Use**

Kolorz Sixty Second Fluoride Foam

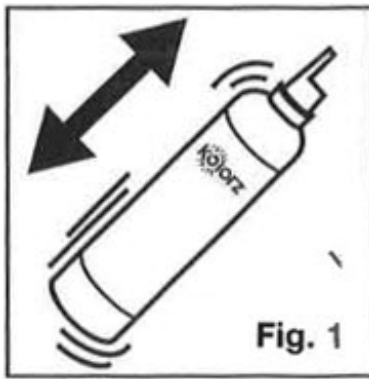
Kolorz Neutral Fluoride Foam

The first time you dispense from a new bottle, gently lift upward on the nozzle to break the protective shipping tab (thin plastic tab located adjacent to "trigger"). If this tab is not broken, there could be an initial surge of foam from the dispenser.

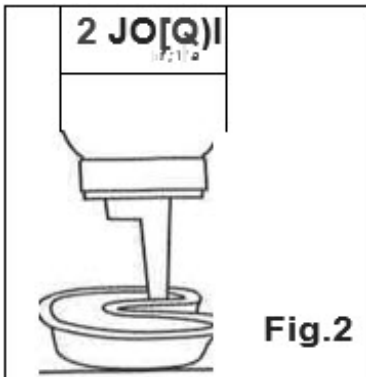


Dosage and Administration:

1. Shake can vigorously before each use. (Fig. 1)



2. Turn can completely upside down to dispense. Point can towards fluoride applicator tray and slowly press the nozzle to fill tray. Use one press per arch, as foam will expand slightly to fill the tray. (Fig. 2)



3. Dry tooth surface and insert tray(s) in mouth.
4. For Kolorz Sixty Second Fluoride Foam: Have patient bite down lightly but firmly for 1 to 4 minutes; For Kolorz Neutral Fluoride Foam: Have patient bite down lightly but firmly for 4 minutes.
5. Remove tray(s) and have patient expectorate excess
6. Instruct patient not to eat, drink, or rinse for at least 30 minutes after application.

How Supplied: Both Kolorz Sixty Second Fluoride Foam and Kolorz Neutral Fluoride Foam are available in 4.4oz. (125g) cans and do not contain chlorofluorocarbon propellant.

Caution: For professional use only. Federal U.S.A. Law prohibits dispensing without prescription.

Warning: Contents under pressure. Do not puncture or incinerate. Store between 55-80° F. Keep from freezing.

kolorz®

Distributed by DMG America
242 South Dean Street
Englewood, NJ 07631 USA
Tel: 201-894-5505
Fax: 201-894-0213
www.dmg-america.com

395490 Rev. 11/13

PRINCIPAL DISPLAY PANEL - 125 g Can Carton - Blue Raspberry

Best Taste...

Guaranteed!

kolorz®

Sixty

Second

Fluoride Foam

Blue Raspberry

APF Topical Fluoride

Acidulated Phosphate Fluoride

1.23% Fluoride Ion

GLUTEN FREE!

Contains

XYLITOL

CAUTION:

For professional use only.

Store at room temperature.

Shake well before each use.

NET WT. 4.4 OZ (125g)

APF Topical Fluoride
Fluoride Foam
 Sixty Second
Blue Raspberry
Kolorz

Best Taste...
 Guaranteed!



INDICATIONS:

For the topical application of fluoride to aid in the protection against dental caries.

Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. See package insert for dosage information.



CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% Fluoride Ion is available from 2.72% Sodium Fluoride. Does not contain chlorofluorocarbon propellant. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

WARNING:

Avoid spraying toward open flame. Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80° F. Keep from freezing.

EMERGENCY RESPONSE:
 Call Infortrac 1-800-535-5053



Made in USA

Distributed by: DMG America LLC.
 242 South Dean Street
 Englewood, NJ 07631
 800-662-6383
 www.dmg-america.com
 Rev. 4/13
 RE-ORDER #766204



+D0337662040

Best Taste...
 Guaranteed!



Sixty Second
Fluoride Foam
Blue Raspberry

APF Topical Fluoride
 Acidulated Phosphate Fluoride
 1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
 For professional use only.
 Store at room temperature.
 Shake well before each use.

Best Taste...
 Guaranteed!



Sixty Second
Fluoride Foam
Blue Raspberry

APF Topical Fluoride
 Acidulated Phosphate Fluoride
 1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
 For professional use only.
 Store at room temperature.
 Shake well before each use.

Best Taste...
 Guaranteed!



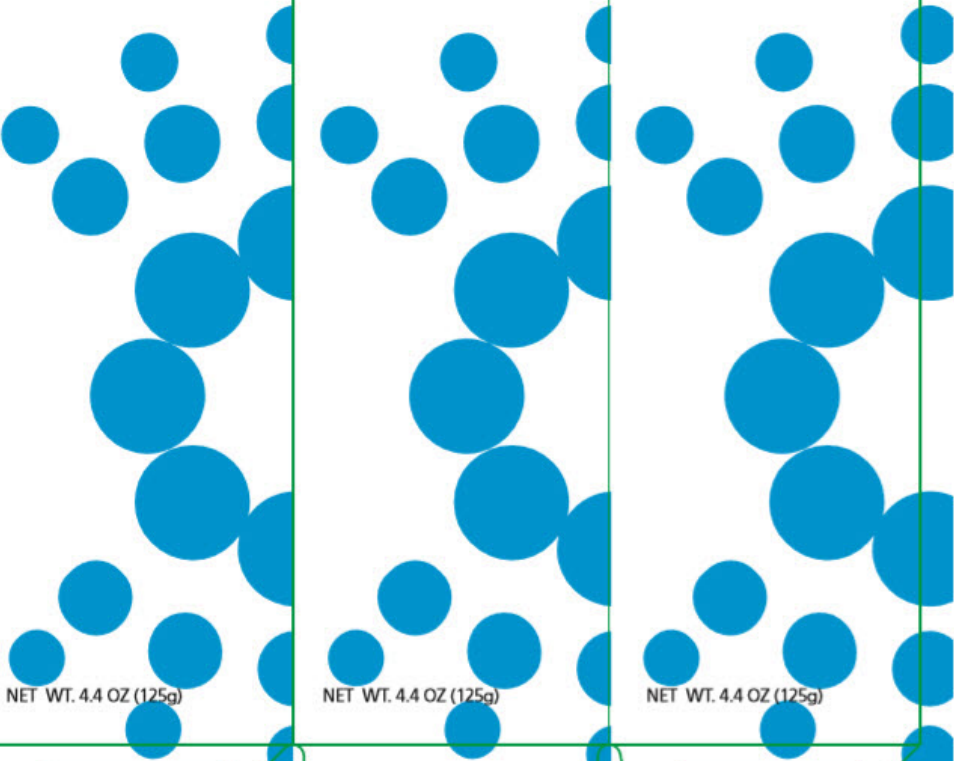
Sixty Second
Fluoride Foam
Blue Raspberry

APF Topical Fluoride
 Acidulated Phosphate Fluoride
 1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
 For professional use only.
 Store at room temperature.
 Shake well before each use.



NET WT. 4.4 OZ (125g)

NET WT. 4.4 OZ (125g)

NET WT. 4.4 OZ (125g)



PRINCIPAL DISPLAY PANEL - 125 g Can Carton - Cherry Cheesecake

Best Taste...
Guaranteed!

kolorz®

Sixty
Second
Fluoride Foam
Cherry Cheesecake

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
For professional use only.

Store at room temperature.

Shake well before each use.

NET WT. 4.4 OZ (125g)

Sixty
Second
Kolorz
Fluoride Foam
Cherry Cheesecake
APF Topical Fluoride

Best Taste...
Guaranteed!



INDICATIONS:

For the topical application of fluoride to aid in the protection against dental caries.

Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. See package insert for dosage information.



CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% Fluoride Ion is available from 2.72% Sodium Fluoride. Does not contain chlorofluorocarbon propellant. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

WARNING:

Avoid spraying toward open flame. Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80° F. Keep from freezing.

EMERGENCY RESPONSE:
Call Infotrac 1-800-535-5053



Made in USA

Distributed by: DMG America LLC
242 South Dean Street
Englewood, NJ 07631
800-662-6383
www.dmg-america.com
Rev. 4/13
RE-ORDER #766202



+D0337662020/



Sixty
Second
Fluoride Foam
Cherry Cheesecake

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
For professional use only.
Store at room temperature.
Shake well before each use.



Sixty
Second
Fluoride Foam
Cherry Cheesecake

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
For professional use only.
Store at room temperature.
Shake well before each use.



Sixty
Second
Fluoride Foam
Cherry Cheesecake

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
For professional use only.
Store at room temperature.
Shake well before each use.

NET WT. 4.4 OZ (125g)

NET WT. 4.4 OZ (125g)

NET WT. 4.4 OZ (125g)



PRINCIPAL DISPLAY PANEL - 125 g Can Carton - Cotton Candy

Best Taste...
Guaranteed!

kolorz[®]

Sixty
Second
Fluoride Foam
Cotton Candy

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
For professional use only.

Store at room temperature.

Shake well before each use.

NET WT. 4.4 OZ (125g)

APF Topical Fluoride
Cotton Candy
Fluoride Foam
Sixty Second



Best Taste...
Guaranteed!



INDICATIONS:

For the topical application of fluoride to aid in the protection against dental caries.

Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. See package insert for dosage information.



CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% Fluoride Ion is available from 2.72% Sodium Fluoride. Does not contain chlorofluorocarbon propellant. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

WARNING:

Avoid spraying toward open flame. Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80° F. Keep from freezing.

EMERGENCY RESPONSE:
Call Infotrac 1-800-535-5053



Made in USA

Distributed by: DMG America LLC.
242 South Dean Street
Englewood, NJ 07631
800-662-6383
www.dmg-america.com
Rev. 4/13

RE-ORDER #766203



++D0337662030++

Best Taste...
Guaranteed!



Sixty Second
Fluoride Foam
Cotton Candy

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
For professional use only.
Store at room temperature.
Shake well before each use.

Best Taste...
Guaranteed!



Sixty Second
Fluoride Foam
Cotton Candy

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
For professional use only.
Store at room temperature.
Shake well before each use.

Best Taste...
Guaranteed!



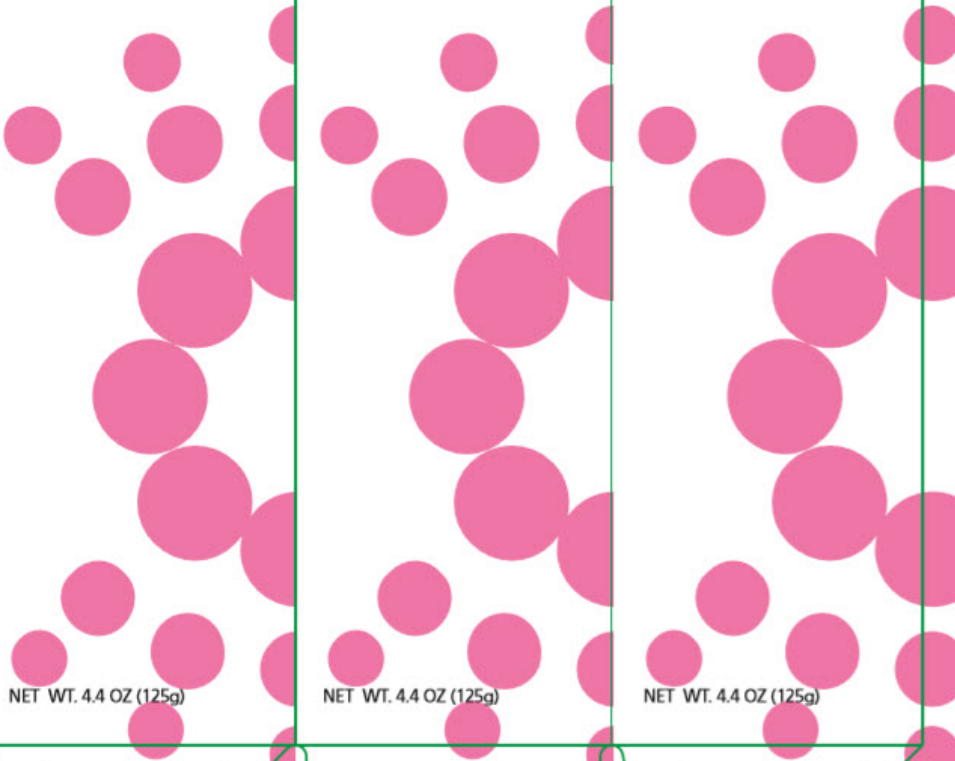
Sixty Second
Fluoride Foam
Cotton Candy

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
For professional use only.
Store at room temperature.
Shake well before each use.



NET WT. 4.4 OZ (125g)

NET WT. 4.4 OZ (125g)

NET WT. 4.4 OZ (125g)



PRINCIPAL DISPLAY PANEL - 125 g Can Carton - Triple Mint

Best Taste...
Guaranteed!

kolorz[®]

Sixty
Second
Fluoride Foam
Triple Mint

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
For professional use only.

Store at room temperature.

Shake well before each use.

NET WT. 4.4 OZ (125g)

APF Topical Fluoride
Fluoride Foam
 Sixty Second
Kolorz
 Triple Mint

Best Taste...
 Guaranteed!



INDICATIONS:

For the topical application of fluoride to aid in the protection against dental caries.

Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. See package insert for dosage information.



CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% Fluoride Ion is available from 2.72% Sodium Fluoride. Does not contain chlorofluorocarbon propellant.

Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

WARNING:

Avoid spraying toward open flame. Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80° F. Keep from freezing.

EMERGENCY RESPONSE:
 Call Infoltrac 1-800-535-5053



Made in USA

Distributed by: DMG America LLC
 242 South Dean Street
 Englewood, NJ 07631
 800-662-6383
 www.dmg-america.com
 Rev. 4/13

RE-ORDER #766201



**D0337662010\$*



Sixty Second
Fluoride Foam
 Triple Mint

APF Topical Fluoride
 Acidulated Phosphate Fluoride
 1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
 For professional use only.
 Store at room temperature.
 Shake well before each use.



Sixty Second
Fluoride Foam
 Triple Mint

APF Topical Fluoride
 Acidulated Phosphate Fluoride
 1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
 For professional use only.
 Store at room temperature.
 Shake well before each use.



Sixty Second
Fluoride Foam
 Triple Mint

APF Topical Fluoride
 Acidulated Phosphate Fluoride
 1.23% Fluoride Ion

GLUTEN FREE!



CAUTION:
 For professional use only.
 Store at room temperature.
 Shake well before each use.

NET WT. 4.4 OZ (125g)

NET WT. 4.4 OZ (125g)

NET WT. 4.4 OZ (125g)



KOLORZ SIXTY SECOND FLUORIDE FOAM BLUE RASPBERRY

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-764
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1.23 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	RASPBERRY (BLUE RASPBERRY)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-764-44	125 g in 1 CAN; Type 0: Not a Combination Product	11/22/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG		11/22/2006	

OTHER	11/22/2006
-------	------------

KOLORZ SIXTY SECOND FLUORIDE FOAM CHERRY CHEESECAKE

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-762
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	1.23 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (CHERRY CHEESECAKE)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-762-44	125 g in 1 CAN; Type 0: Not a Combination Product	11/22/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/22/2006	

KOLORZ SIXTY SECOND FLUORIDE FOAM COTTON CANDY

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-763
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	1.23 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-763-44	125 g in 1 CAN; Type 0: Not a Combination Product	11/22/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/22/2006	

KOLORZ SIXTY SECOND FLUORIDE FOAM TRIPLE MINT

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-761
---------------------	-------------------------	---------------------------	---------------

Route of Administration	DENTAL
--------------------------------	--------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	1.23 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (TRIPLE MINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-761-44	125 g in 1 CAN; Type 0: Not a Combination Product	11/22/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/22/2006	

Labeler - DMG AMERICA, LLC (106792427)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	MANUFACTURE(25047-761, 25047-762, 25047-763, 25047-764) , PACK(25047-761, 25047-762, 25047-763, 25047-764) , LABEL(25047-761, 25047-762, 25047-763, 25047-764)