#### NAFRINSE PACKETS BUBBLE GUM- sodium fluoride powder Young Dental Manufacturing Co 1, 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.

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### Inactives

Saccharin Sodium, Potassium Sorbate, Citric Acid, Flavoring

Dye

## Warning:

This Packet contains sodium fluoride powder, contents poisonous if swallowed. keep away from children. Store in a dry place at controlled room temperature. For professional use only.

#### DO NOT SWALLOW

MISSUSE If child swallows dispensed amount of mouth rinse in a cup:

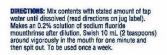
1. Do not panic -this amount should not hurt the child

2. In rare cases the child may feel slightly nauseous.

The child may have a serving of milk or ice cream to relieve the nausea. EMERGENCY TREATMENT If a child swallows more than one dispensed amount in a cup or powder contents of the fluoride mouth rinse packet call the Poison Control Center at 800-222-1222

## Directions

Mix contents with stated amount of tap water until dissolved (read directions on jug label) Makes an 0.2 % solution of sodium fluoride mouthrinse aftert dilution. Swish 10 ml (2 teaspoons) around vigorously in the mouth for one minute and then spit out. To be used once a week.



DIRECTIONS: Mix contents with stated amount of tap water until dissolved (read directions on jug label). Makes an 0.2% solution of solutim fluoride mounthrinse after dilution. Swish 10 mL (2 taspoons) around vigorously in the mount for one minute and then spit out. To be used once a week. DIRECTIONS: Mix contents with stated amount of tap water until dissolved (read directions on jug label). Makes an 0.2% solution of solution fluoride mounthrinse after dilution. Swish 10 m. (2 teaspoons) around vigorously in the mouth for one minute and then splt out. To be used once a week.

Sedim Flooride Monthins Powder South Flooride Monthins Powder Currone: First Action Contractions Flooride Transformer Flooring Flooride Monthing Flooride Flooride Monthing Flooride Contraction Section Flooride Flooride Monthing Flooride Mathing: Do Not Swallow.

TEAR RESISTANT PACKET



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odium fluoride powder						
Product Information	n					
Product T ype		HUMAN PRESCRIPTION DRUG	Item Code (Source)		NDC:0273-8018	
Route of Administration	n	DENTAL				
Active Ingredient/A	ctive Moi	e ty				
Ingredient Name				Basis of Strength		Strength
Sodium Fluoride (UNII: 8	odium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O) Fluoride Ion					1g in 1g
Inactive Ingredients	5					
Inactive Ingredients	3	Ingredient Name			St	rength
Inactive Ingredients SACCHARIN SODIUM (UI		<b>Ingredient Name</b> 40TY)			St	rength
Inactive Ingredients SACCHARIN SODIUM (UI Potassium Sorbate (UNII:	NII: SB8ZUX	40 TY)			St	rength
SACCHARIN SODIUM (UI	NII: SB8ZUX 1VPU26JZZ4	40 TY) 4)			St	rength
SACCHARIN SODIUM (UI Potassium Sorbate (UNII:	NII: SB8ZUX 1VPU26JZZ4	40 TY) 4)			St	rength
SACCHARIN SODIUM (UI Potassium Sorbate (UNII:	NII: SB8ZUX 1VPU26JZZ I <b>D</b> (UNII: XF4	40 TY) 4)			St	rength
SACCHARIN SODIUM (UI Potassium Sorbate (UNII: ANHYDROUS CITRIC AC	NII: SB8ZUX 1VPU26JZZ I <b>D</b> (UNII: XF4	40 TY) 4)	S	core	St	rength
SACCHARIN SODIUM (UI Potassium Sorbate (UNII: ANHYDROUS CITRIC AC Product Characteris Color	NII: SB8ZUX 1VPU26JZZ I <b>D</b> (UNII: XF4	40 TY) 4)		core	St	rength
SACCHARIN SODIUM (UI Potassium Sorbate (UNII: ANHYDROUS CITRIC AC Product Characteris Color Shape	NII: SB8ZUX 1VPU26JZZ ID (UNII: XF4 Stics	40 TY) 4)	S		St	rength

Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
<b>1</b> NDC:0273-8018-03	50 in 1 PACKAGE	09/21/2017					
1	3 g in 1 PACKET; Type 0: Not a Combination Product						
Marketing Info	vrmation						
Marketing Info	ormation						
Marketing Info		Marketing Start Date	Marketing End Date				

Labeler - Young Dental Manufacturing Co 1, LLC. (006309355)

**Registrant** - Young Dental Manufacturing Co 1, LLC. (006309355)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Medical Products Laboratories, Inc.		002290302	manufacture(0273-8018)

Revised: 12/2018

Young Dental Manufacturing Co 1, LLC.