PCXX ONE MINUTE COOL PEPPERMINT- sodium fluoride gel Ross Healthcare 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.

PCXX ONE MINUTE COOL PEPPERMINT

sodium fluoride gel

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-054	
Route of Administration	topical			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	.02 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	.001 mg in 1 mL		

Product Characteristics				
Color	blue	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:62007-054-16	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/03/2015	

Labeler - Ross Healthcare Inc. (244249012)

Registrant - Ross Healthcare Inc. (244249012)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ross Healthcare Inc.		244249012	manufacture(62007-054)	

Revised: 2/2015 Ross Healthcare Inc.