MEDICATED DANDRUFF - selenium sulfide shampoo
AMERICAN SALES COMPANY

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.

DRUG FACTS

ACTIVE INGREDIENT

SELENIUM SULFIDE 1%

PURPOSE

ANTI-DANDRUFF

USES

FOR RELIEF OF FLAKING AND ITCHING DUE TO DANDRUFF, AND SEBORRHEIC DERMATITIS, AND TO HELP PREVENT THE CHANCE OF RE-OCCURENCE.

WARNINGS

FOR EXTERNAL USE ONLY.

ASK A DOCTOR BEFORE USING IF YOU HAVE

SEBORRHEIC DERMATITIS IN AREAS OTHER THAN THE SCALP.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH THE EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER. FOR USE ON COLOR-TREATED OR PERMED HAIR, RINSE THOROUGHLY.

STOP USE AND ASK A DOCTOR IF

CONDITION WORSENS OR DOES NOT IMPROVE AFTER REGULAR USE OF THIS PRODUCT AS DIRECTED.

KEEP OUT OF REACH OF CHILDREN

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

SHAKE WELL. SHAMPOO, THEN RINSE THOROUGHLY. FOR BEST RESULTS, USE AT LEAST TWICE A WEEK OR AS DIRECTED BY A DOCTOR.

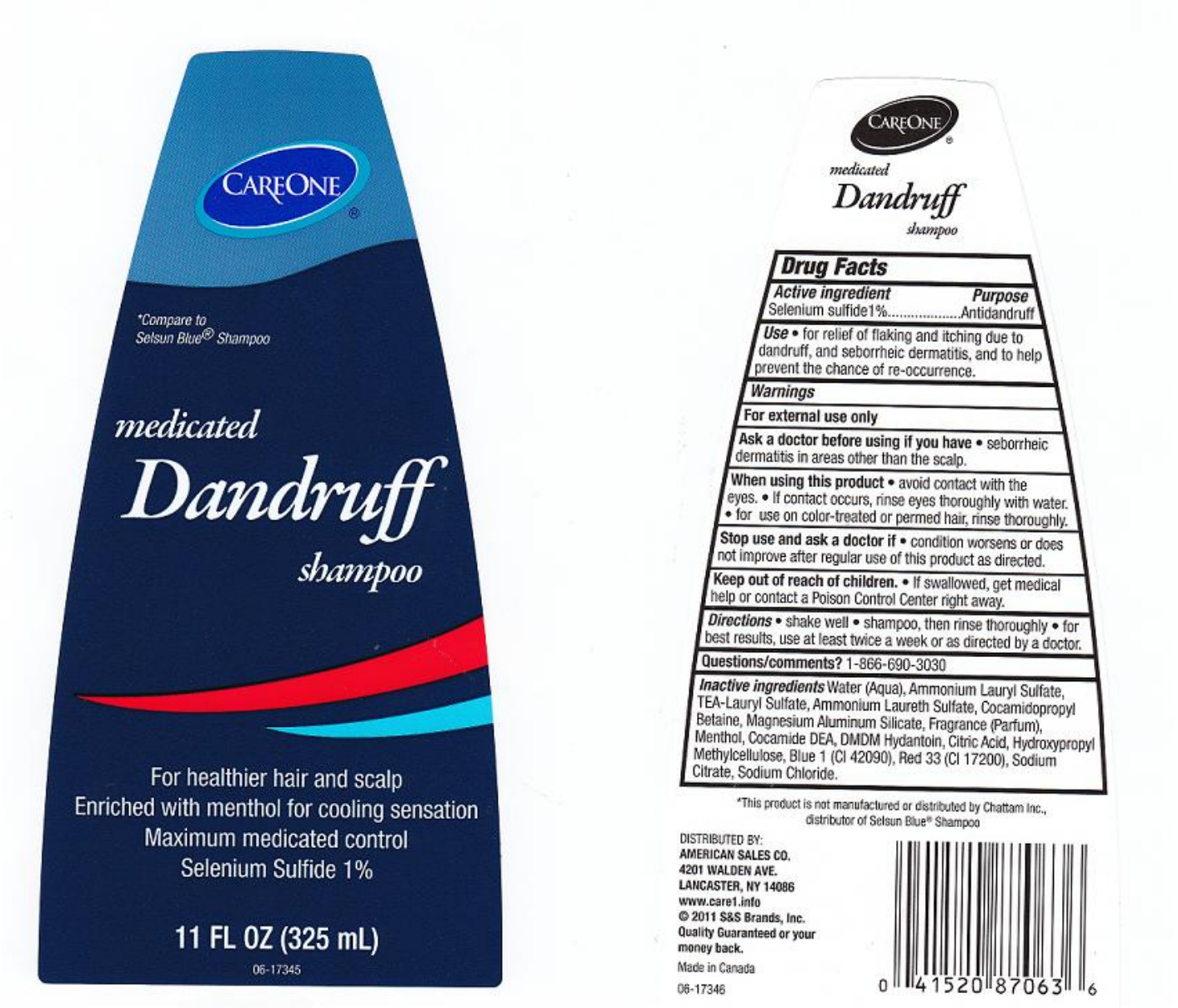
QUESTIONS/COMMENTS?

1-866-690-3030

INACTIVE INGREDIENTS

WATER (AQUA), AMMONIUM LAURYL SULFATE, TEA-LAURYL SULFATE, AMMONIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, MAGNESIUM ALUMINUM SILICATE, FRAGRANCE, MENTHOL, COCAMIDE DEA, DMDM HYDANTOIN, CITRIC ACID, HYDROXYPROPYL METHYLCELLULOSE, BLUE 1, RED 33, SODIUM CITRATE, SODIUM CHLORIDE

Front and Back labels



MEDICATED DANDRUFF

selenium sulfide shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-614
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM - UNII:H6241UJ22B)	SELENIUM SULFIDE	1 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
TROLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
MENTHOL (UNII: L7T10EIP3A)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:41520-614-11	325 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	08/19/2011	

Labeler - AMERICAN SALES COMPANY (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 8/2011 AMERICAN SALES COMPANY