ANUBISMED- sodium bicarbonate, aloe barbadensis leaf juice, imidazolidinyl urea liquid
ANUBIS COSMETICS SL

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.

ANUBISMED

sodium bicarbonate, aloe barbadensis leaf juice, imidazolidinyl urea liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83021-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IMIDUREA (UNII: M629807ATL) (IMIDUREA - UNII:M629807ATL)	IMIDUREA	0.25 g in 50 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X) (ALOE VERA LEAF - UNII:ZY81Z83H0X)	ALOE VERA LEAF	0.15 g in 50 mL

WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	45.8293 mL in 50 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	3.75 g in 50 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.02 g in 50 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.00035 g in 50 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.00035 g in 50 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83021-400-50	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	10/26/2022	05/10/2027

Labeler - ANUBIS COSMETICS SL (468680293)

Registrant - GDC OF FLORIDA IMPORTS, INC. (807003988)

Establishment

Name	Address	ID/FEI	Business Operations
ANUBIS COSMETICS SL		468680293	manufacture(83021-400)

Revised: 9/2023 ANUBIS COSMETICS SL