



© August 2014

Introduction Type: ☐ New Item

☒ Final Version

Date: 6/1/17

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																																																												
Company Name: Avkare, Inc. Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text"/> DESI: <input type="text"/> Application: ANDA				a. Temperature - Indicate the USP temperature range for this product. Temperature Range: <input type="text"/> Controlled Room - between 20 and 25 C (68° - 77°) Other Temperature Range Requirement (write in): <input type="text"/>																																																																																												
DUNS: 79560394 Proprietary Name (if Applicable) and Established Name: Hydrocortisone Acetate Suppositories 25mg 12ct Selling Unit NDC: 50268-0411-12 Individual Unit NDC: <input type="text"/> UPC: <input type="text"/> UDI: <input type="text"/> CVX Code: <input type="text"/> MXV Code: <input type="text"/>				b. Contact for temperature excursion questions: Name: <input type="text"/> Number: <input type="text"/> Group E-mail: <input type="text"/>																																																																																												
Description: Hydrocortisone Acetate Suppositories 25mg 12ct Active Ingredient(s): <input type="text"/>				c. Special regulations for product in any states? <input type="checkbox"/> No Special returns requirements for this product? <input type="text"/>																																																																																												
URL for Additional Product Information: <input type="text"/> Address: 815 North First Street City: Puucki State: TN Zip: 38478 Key Contact: Kim Bracey Email: kbracey@avkare.com Phone Number: 931-908-0028 Fax: 931-292-6229 Product Therapeutic Classification: <input type="text"/>				d. Store product (unit of sale) upright? <input type="checkbox"/> No e. Shelf life: <input type="text"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																																																																												
ADDITIONAL PRODUCT INFORMATION Is the Product... a legend device? <input type="checkbox"/> No reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No Is the Product... <input type="checkbox"/> Direct And Drop-Ship Is the Product... <input type="checkbox"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No If Unit Dose NDC, indicate NDC here: <input type="text"/> Country of Origin: <input type="text"/> USA Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes				PRODUCT DESCRIPTION INFORMATION Size: 12ct Strength: 25mg Dosage Form: Suppository Product Shape: bullet shaped with one pointed Product Color: off-white Product Imprint: <input type="text"/>																																																																																												
FOR GENERIC DRUG PRODUCTS I. Orange Book Rating: <input type="text"/> Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: <input type="text"/>				PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? <input type="text"/> (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input type="text"/> Each Gram Milliliter																																																																																												
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> No GLN: <input type="text"/> Is product exempt from DSCSA? <input type="checkbox"/> No If yes, select exemption: <input type="text"/> Other exemption - Write in: <input type="text"/> Is product repackaged? <input type="checkbox"/> No If Yes, was original product purchased direct from mfr? <input type="checkbox"/> Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes If yes, attach documentation from FDA. Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No				ITEM AND PACKING INFORMATION <table border="1"><thead><tr><th rowspan="2">Item:</th><th rowspan="2">Weight Lbs.</th><th colspan="3">Dimensions (US msmts.)</th><th rowspan="2">Volume (Cups)</th><th rowspan="2"># Pieces:</th></tr><tr><th>Depth</th><th>Height</th><th>Width</th></tr></thead><tbody><tr><td>Box/ Carton/ Bundle/ Inner Pack:</td><td>0.08lbs</td><td>1</td><td>2.375</td><td>4.625</td><td>10.984375</td><td>1</td></tr><tr><td>Case:</td><td>4.2lbs</td><td>12.5</td><td>9.5</td><td>5</td><td>593.75</td><td>24</td></tr><tr><td>Pallet:</td><td></td><td></td><td></td><td></td><td>0</td><td></td></tr><tr><td>UPC:</td><td>Case:</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td>Carton:</td><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>				Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cups)	# Pieces:	Depth	Height	Width	Box/ Carton/ Bundle/ Inner Pack:	0.08lbs	1	2.375	4.625	10.984375	1	Case:	4.2lbs	12.5	9.5	5	593.75	24	Pallet:					0		UPC:	Case:							Carton:																																																	
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WHOLESALE USE ONLY: Signature: <input type="text"/>																																																																																																

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.
See new p. 3 for Designated Drop Ship Only.