

© August 2014

Introduction Type: ☐ New Item

☒ Final Version

Date: 10/18/17

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																																											
Company Name: <u>Avkare, Inc.</u> Application: <u>ANDA</u> Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): _____ DUNS: <u>79560394</u> Proprietary Name (if Applicable) and Established Name: <u>Acitretin 10mg Capsule 30ct</u> Selling Unit NDC: <u>42291-0086-30</u> Individual Unit NDC: _____ UPC: _____ UDI: _____ CVX Code: _____ MVX Code: _____ Description: <u>Acitretin 10mg Capsule 30ct</u> Active Ingredient(s): _____ URL for Additional Product Information: _____ Address: <u>815 North First Street</u> Address 2: _____ City: <u>Pasacki</u> State: <u>IN</u> Zip: <u>38478</u> Key Contact: <u>Kim Bracey</u> Email: <u>kbracey@avkare.com</u> Phone Number: <u>931-908-0028</u> Fax: <u>931-292-6229</u> Product Therapeutic Classification: _____				a. Temperature - Indicate the USP temperature range for this product. Temperature Range: <u>Controlled Room - between 20 and 25 C (68° - 77°)</u> Other Temperature Range Requirement (write in): _____ Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No b. Contact for temperature excursion questions: Name: _____ Number: _____ Group E-mail: _____ c. Special regulations for product in any states? <input type="checkbox"/> No Special returns requirements for this product? _____ d. Store product (unit of sale) upright? <input type="checkbox"/> No Protect product (unit of sale) from light? _____ e. Shelf life: Initial shelf life at launch (if different): _____ Months																																																																											
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> 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... <u>Direct And Drop-Ship</u> Is the Product... _____ If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No If Unit Dose NDC, indicate NDC here: _____ Country of Origin <u>USA</u> Is this product covered under the Trade Agreements Act (TAA)? <input checked="" type="checkbox"/> Yes </div> <div style="width: 48%;"> PRODUCT DESCRIPTION INFORMATION Size: <u>30ct</u> Strength: <u>10mg</u> Dosage Form: <u>capsule</u> Product Shape: <u>capsule</u> Product Color: <u>yellow, white</u> Product Imprint: <u>80</u> </div> </div>				ORDER INFORMATION <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In _____ </td> <td style="width: 50%; vertical-align: top;"> What is the NDC selling unit? <u>1 Bottle of 30 capsules</u> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? Each _____ Inner/Carton/Pack _____ Case _____ </td> </tr> </table>				Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In _____	What is the NDC selling unit? <u>1 Bottle of 30 capsules</u> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? Each _____ Inner/Carton/Pack _____ Case _____																																																																						
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FOR GENERIC DRUG PRODUCTS I. Orange Book Rating: <u>AB</u> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: <u>Soriatane®</u>				PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? _____ Rx billing unit to pharmacy: (Write-in, e.g. 1 Vial) Each _____ Gram _____ Milliliter _____																																																																											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> No GLN: _____ Is product exempt from DSCSA? <input type="checkbox"/> No If yes, select exemption: Other exemption - Write in: _____ Is product repackaged? <input type="checkbox"/> No If Yes, was original product purchased direct from mfr? <input type="checkbox"/> No 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 style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Item:</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US smmts.)</th> <th rowspan="2">Volume (Gals)</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>0.073</td> <td>1.496</td> <td>3.543</td> <td>1.496</td> <td>6.224</td> <td>1</td> </tr> <tr> <td>Case:</td> <td>0.695</td> <td>7.2</td> <td>4.5</td> <td>4.5</td> <td>145.8</td> <td>6</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 smmts.)			Volume (Gals)	# Pieces:	Depth	Height	Width	Box/Carton/Bundle/Inner Pack:	0.073	1.496	3.543	1.496	6.224	1	Case:	0.695	7.2	4.5	4.5	145.8	6	Pallet:					0		UPC:	Case:							Carton:																																
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*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. Signature: _____																																																																											