

© August 2014

Introduction Type: ☐ New Item

☒ Final Version

Date: 6/1/17

| PRODUCT INFORMATION | | | | SPECIAL HANDLING AND STORAGE REQUIREMENTS* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---------------|------------------------|--------|---|---------------|-------------------|-------|-------|-------------|------------------------|----------|---------|---------------|-----------|----------|---------|-------|-------------------------------|---------|--------|-------|-------|----------|----|-------|--|--|--|--|---|--|---------|--------|------|-----|---|--------|----|------|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Company Name: <u>Avkare, Inc.</u> Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <u> </u> DESI: <u> </u> Application: <u>ANDA</u> DUNS: <u>79560394</u> Proprietary Name (if Applicable) and Established Name: <u>Hydrocortisone Acetate Suppositories 25mg 24ct</u> Selling Unit NDC: <u>50268-0411-24</u> Individual Unit NDC: <u> </u> UPC: <u> </u> UDI: <u> </u> CVX Code: <u> </u> MVX Code: <u> </u> Description: <u>Hydrocortisone Acetate Suppositories 25mg 24ct</u> Active Ingredient(s): <u> </u> URL for Additional Product Information: <u> </u> Address: <u>615 North First Street</u> City: <u>Pittsford</u> State: <u>NY</u> Zip: <u>13478</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: <u> </u> | | | | 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): <u> </u> Is this product to be shipped to customers on ice? <u>No</u> Is this product to be shipped to customers on dry ice? <u>No</u> b. Contact for temperature excursion questions: Name: <u> </u> Number: <u> </u> Group E-mail: <u> </u> c. Special regulations for product in any states? <u>No</u> Special returns requirements for this product? <u> </u> d. Store product (unit of sale) upright? <u>No</u> Protect product (unit of sale) from light? <u> </u> e. Shelf life: Initial shelf life at launch (if different): <u> </u> Months | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> ADDITIONAL PRODUCT INFORMATION Is the Product... a legend device? <u>No</u> reverse numbered? <u>No</u> co-licensed? <u>No</u> Is the Product... <u>Direct And Drop-Ship</u> Is the Product... <u> </u> If Unit Dose, is item bar coded to unit dose for hospital scanning? <u>No</u> If Unit Dose NDC, indicate NDC here: <u> </u> Country of Origin <u>USA</u> Is this product covered under the Trade Agreements Act (TAA)? <u>Yes</u> </div> <div style="width: 48%;"> PRODUCT DESCRIPTION INFORMATION Size: <u>24ct</u> Strength: <u>25mg</u> Dosage Form: <u>Suppository</u> Product Shape: <u>bullet shaped with one pointed</u> Product Color: <u>off-white</u> Product Imprint: <u> </u> </div> </div> | | | | ORDER INFORMATION <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> 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 <u> </u> </div> <div style="width: 48%;"> What is the NDC selling unit? <u>1 Box of 24 suppositories</u> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <u> </u> Yes If Yes, how many of which package type? Each <u> </u> Inner/Carton/Pack <u>1</u> Case <u> </u> </div> </div> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| FOR GENERIC DRUG PRODUCTS I. Orange Book Rating: <u> </u> Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: <u> </u> | | | | PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? <u> </u> Rx billing unit to pharmacy: (Write-in, e.g. 1 Vial) <u> </u> Each <u> </u> Gram <u> </u> Milliliter <u> </u> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Does supplier meet DSCSA definition of manufacturer? <u>No</u> GLN: <u> </u> Is product exempt from DSCSA? <u>No</u> If yes, select exemption: Other exemption - Write in: <u> </u> Is product repackaged? <u>No</u> If Yes, was original product purchased direct from mfr? <u> </u> Is product sold by manufacturer's exclusive distributor? <u>Yes</u> If yes, attach documentation from FDA. Has FDA granted waiver/exception/exemption for product? <u>No</u> | | | | ITEM AND PACKING INFORMATION <table border="1" style="width: 100%; border-collapse: collapse; font-size: 0.8em;"> <thead> <tr> <th rowspan="2">Item:</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</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>0.15lbs</td> <td>2</td> <td>2.375</td> <td>4.625</td> <td>21.96875</td> <td>1</td> </tr> <tr> <td>Case:</td> <td></td> <td></td> <td></td> <td></td> <td>0</td> <td></td> </tr> <tr> <td>Pallet:</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>UPC:</td> <td></td> <td></td> <td></td> <td></td> <td>0</td> <td></td> </tr> </tbody> </table> | | | | Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Gals) | # Pieces: | Depth | Height | Width | Box/Carton/Bundle/Inner Pack: | 0.15lbs | 2 | 2.375 | 4.625 | 21.96875 | 1 | Case: | | | | | 0 | | Pallet: | 4.2lbs | 12.5 | 9.5 | 5 | 593.75 | 24 | UPC: | | | | | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Gals) | # Pieces: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | Depth | Height | Width | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Box/Carton/Bundle/Inner Pack: | 0.15lbs | 2 | 2.375 | 4.625 | 21.96875 | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Case: | | | | | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pallet: | 4.2lbs | 12.5 | 9.5 | 5 | 593.75 | 24 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| UPC: | | | | | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| GTIN PRODUCT INFORMATION <table border="1" style="width: 100%; border-collapse: collapse; font-size: 0.8em;"> <thead> <tr> <th rowspan="2">Serialized?</th> <th rowspan="2">If not, when?</th> <th rowspan="2">Items aggregated?</th> <th colspan="4">Level</th> <th colspan="4">Unit</th> <th rowspan="2">Quantity</th> <th rowspan="2">GTIN-14</th> </tr> <tr> <th>Item</th> <th>Box/Carton/Bundle/Inner Pack</th> <th>Case</th> <th>Pallet</th> <th>20</th> <th>20</th> <th>20</th> <th>20</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> | | | | Serialized? | If not, when? | Items aggregated? | Level | | | | Unit | | | | Quantity | GTIN-14 | Item | Box/Carton/Bundle/Inner Pack | Case | Pallet | 20 | 20 | 20 | 20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | COST INFORMATION Regular Cost <u>\$515.98</u> Invoice Cost (WAC) (\$) <u>\$246.87</u> Federal Excise Tax Per Unit of Sale <u> </u> As of date: <u>6/1/17</u> | | | |
| Serialized? | If not, when? | Items aggregated? | Level | | | | Unit | | | | Quantity | GTIN-14 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | Item | Box/Carton/Bundle/Inner Pack | Case | Pallet | 20 | 20 | 20 | 20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| WHOLESALE USE ONLY: Vendor #: <u> </u> Whsl. Code #: <u> </u> Fineline Code: <u> </u> | | | | Signature: <u> </u> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

*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.