



2/23/16

<b>PRODUCT INFORMATION</b>		<b>SPECIAL HANDLING AND STORAGE REQUIREMENTS*</b>																																														
Company Name: <u>AvKARE, INC</u> Application: <u>ANDA</u> Application Number for <u>NDA/ANDA/BLA, Med Device:</u> <u>OTC</u> Rx Product/Proprietary Name: <u>Calcium Carbonate Chewable 500mg Tablet 30ct</u> NDC: <u>50268-0149-13</u> UPC: _____ CVX Code: _____      MVX Code: _____ Description: <u>Calcium Carbonate Chewable 500mg Tablet 30ct</u> Active Ingredients: _____ URL for Additional Product Information: _____ Address: <u>615 North First Street</u> Address 2: _____ City: <u>Pulaski</u> State: <u>TN</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>		a. Temperature – Indicate the USP temperature range for this product. <input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F) <input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F) <input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F) <input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) <input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F) <input type="checkbox"/> VI. Other Temperature Range Requirement _____ (write in) _____ <input type="checkbox"/> VII. No Requirement																																														
<b>FOR GENERIC DRUG PRODUCTS</b>		b. Contact for temperature excursion questions: Name: _____ Number: _____ Is this product to be shipped to customers on ice? _____ Is this product to be shipped to customers on dry ice? _____																																														
I. Orange Book Rating: <u>NA</u> II. Brand Name: <u>NA</u> III. Generic Equivalent for Brand: <u>Calcium Carbonate Chewable</u>		c. Special regulations for product in certain states? _____ Special returns requirements for this product? _____																																														
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>																																																
Does supplier meet DSCSA definition of manufacturer?      Yes      No      DUNS: <u>796560394</u> Is product exempt from DSCSA?      No      Yes If yes, select exemption: _____ Other exemption - Write in: _____ Is product repackaged?      Yes      No      If Yes, was original product purchased direct from mfr?      Yes      No Is product sold by manufacturer's exclusive distributor?      Yes      No Are any waivers granted for product ID/barcode?      No      Yes, attach documentation from FDA																																																
<b>ADDITIONAL PRODUCT INFORMATION</b>		<b>ITEM AND PACKING INFORMATION</b>																																														
Is the Product... <u>Direct and Drop Ship</u> Legend Device?      No      Yes State Control?      No      Yes ARCOs reportable?      No      Yes Co-Licensed?      No      Yes Controlled Substance?      No      Yes Schedule No.? _____ (incl. N for non-narcotic) Controlled Substance Code: _____ Hazardous Material/Cytotoxic Agent?      No      Yes Is Item...      Unit Dose If Unit Dose, is item bar coded to unit dose for hospital scanning?      Yes      No Is it reverse numbered?      No      Yes		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th rowspan="2">Item:</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2"># Pieces:</th> </tr> <tr> <th>Depth</th> <th>Height</th> <th>Width</th> </tr> <tr> <td><u>Box/ Carton:</u></td> <td><u>0.3</u></td> <td><u>2.00"</u></td> <td><u>4.25"</u></td> <td><u>3.25"</u></td> <td></td> <td><u>1</u></td> </tr> <tr> <td><u>Case:</u></td> <td><u>3</u></td> <td><u>9.50"</u></td> <td><u>4.50"</u></td> <td><u>6.50"</u></td> <td></td> <td><u>10</u></td> </tr> <tr> <td><u>Pallet:</u></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><u>UPC:</u></td> <td><u>Case:</u></td> <td colspan="4"></td> <td></td> </tr> <tr> <td></td> <td><u>Carton:</u></td> <td colspan="4"></td> <td></td> </tr> </table>		Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	Depth	Height	Width	<u>Box/ Carton:</u>	<u>0.3</u>	<u>2.00"</u>	<u>4.25"</u>	<u>3.25"</u>		<u>1</u>	<u>Case:</u>	<u>3</u>	<u>9.50"</u>	<u>4.50"</u>	<u>6.50"</u>		<u>10</u>	<u>Pallet:</u>							<u>UPC:</u>	<u>Case:</u>							<u>Carton:</u>					
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<b>ORDER INFORMATION</b>		<b>COST INFORMATION</b>																																														
What is the NDC selling unit? <u>30 pills per box</u> <u>10 boxes per case</u> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity?      Yes      No If Yes, how many of which package type? <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>Each</td> <td></td> </tr> <tr> <td>Inner/ Carton/ Pack</td> <td></td> </tr> <tr> <td>Case</td> <td><u>1</u></td> </tr> </table>		Each		Inner/ Carton/ Pack		Case	<u>1</u>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th>Regular Cost Per Unit of Sale (\$)</th> <th>Invoice Cost (WAC) (\$)</th> <th>Federal Excise Tax Per Unit of Sale</th> </tr> <tr> <td><u>\$8.21</u></td> <td><u>\$6.86</u></td> <td></td> </tr> </table>		Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale	<u>\$8.21</u>	<u>\$6.86</u>																																		
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<b>PHARMACY ORDER / BILL UNIT</b>		<b>Other Product Information</b>																																														
Rec. sell unit to customer? _____ (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter		Size/Strength/Form: <u>30ct/500mg/Tablet</u> Product Shape: <u>round</u> Product Color: <u>white</u> Product Imprint: _____																																														
<b>WHOLESALE USE ONLY:</b>																																																
Vendor #: _____ Whsl. Code #: _____ Finline Code: _____		As of date: <u>2/23/16</u>																																														