

PRODUCT INFORMATION										SPECIAL HANDLING AND STORAGE REQUIREMENTS																																																									
Company Name: AVKARE, Inc.										Application Number: NDA/ANDA/BLA (drug): PMA/510(k)(med device): 205530 Application: ANDA																																																									
DUNS: 796560394																																																																			
Proprietary Name (if Applicable) and Established Name: Acetazolamide 125mg Tablet 100ct																																																																			
Selling Unit NDC: 42291-0089-01										Individual Unit NDC: _____ UPC: _____																																																									
UDI: _____ CVX Code: _____ MVX Code: _____																																																																			
Description: Acetazolamide 125mg Tablet 100ct																																																																			
Active Ingredient(s): _____																																																																			
URL for Additional Product Information: _____																																																																			
Address: 615 North First Street										Address 2: _____																																																									
City: Pulaski										State: TN Zip: 38478																																																									
Key Contact: Kim Bracey										Email: kbracey@avkare.com																																																									
Phone Number: 931-908-0028										Fax: 931-292-6229																																																									
Product Therapeutic Classification: _____																																																																			
ADDITIONAL PRODUCT INFORMATION										PRODUCT DESCRIPTION INFORMATION																																																									
Is the Product... a legend device? No reverse numbered? No co-licensed? No Is the Product... Direct And Drop-Ship Is the Product... _____										Size: 100ct Strength: 125mg Dosage Form: Tablet Product Shape: round Product Color: white Product Imprint: HP;287																																																									
If Unit Dose, is item bar coded to unit dose for hospital scanning? _____ If Unit Dose NDC, indicate NDC here: _____ Country of Origin USA Is this product covered under the Trade Agreements Act (TAA)? Yes																																																																			
FOR GENERIC DRUG PRODUCTS																																																																			
I. Orange Book Rating: AB										<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable																																																									
II. Generic Equivalent to What Brand?: Diamox																																																																			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																																																			
Does supplier meet DSCSA definition of manufacturer? No										GLN: _____																																																									
Is product exempt from DSCSA? No																																																																			
If yes, select exemption: Other exemption - Write in: _____																																																																			
Is product repackaged? No										If Yes, was original product purchased direct from mfr? _____																																																									
Is product sold by manufacturer's exclusive distributor? Yes										If yes, attach documentation from FDA. _____																																																									
Has FDA granted waiver/exception/exemption for product? No																																																																			
GTIN PRODUCT INFORMATION																																																																			
Serialized? _____																																																																			
If not, when? _____																																																																			
Items aggregated? _____																																																																			
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<p>a. Temperature – indicate the USP temperature range for this product. Temperature Range: _____ Controlled Room – between 20 and 25 C (68° – 77°) Other Temperature Range Requirement (write in) _____</p> <p>Is this product to be shipped to customers on ice? No</p> <p>Is this product to be shipped to customers on dry ice? No</p> <p>b. Contact for temperature excursion questions: Name: _____ Number: _____ Group E-mail: _____</p> <p>c. Special regulations for product in any states? No Special returns requirements for this product? _____</p> <p>d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? _____</p> <p>e. Shelf life: Initial shelf life at launch (if different): _____ Months _____ Months</p>																																																																			
ORDER INFORMATION																																																																			
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 Power Multi <input type="checkbox"/> Other: Write In _____										What is the NDC selling unit? 1 Box 100 Tablets (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? _____ Yes																																																									
										If Yes, how many of which package type? <input type="checkbox"/> Each <input type="checkbox"/> Inner/ Carton/ Pack <input checked="" type="checkbox"/> Case																																																									
PHARMACY ORDER / BILL UNIT																																																																			
Rec. sell unit to customer? _____										Rx billing unit to pharmacy: <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																																																									
(Write-in, e.g. 1 Vial)																																																																			
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	Carton:																																																																		
COST INFORMATION																																																																			
Regular Cost \$217.99										Vendor #: _____																																																									
Invoice Cost (WAC) (\$) \$97.16										Whsl. Code #: _____																																																									
Federal Excise Tax Per Unit of Sale _____										Fineline Code: _____																																																									
As of date: 5/30/17																																																																			
<p>*Please provide any additional information on page 2.</p> <p align="center">Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.</p> <p align="center">See new p. 3 for Designated Drop Ship Only.</p>																																																																			