

© August 2014

Introduction Type: ☐ New Item☒ Final Version

Date: 9/26/17

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																
Company Name: Avkare, Inc.				Application: ANDA																																																
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203576																																																				
DUNS: 796560394																																																				
Proprietary Name (If Applicable) and Established Name: Niacin ER 500mg Tablet UD30																																																				
Selling Unit NDC: 50268-0584-13				Individual Unit NDC: 																																																
UDI				CVX Code: MVX Code: 																																																
Description: Niacin ER 500mg Tablet UD30																																																				
Active Ingredient(s): 																																																				
URL for Additional Product Information: 																																																				
Address: 815 North First Street				Address 2: 																																																
City: Pittsford				State: NY Zip: 13478																																																
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? <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"/> Unit Dose				Size: 30 Strength: 500mg Dosage Form: Tablet Product Shape: round Product Color: orange Product Imprint: AN;321																																																
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> Yes																																																				
If Unit Dose NDC, indicate NDC here: 50268-0584-13																																																				
Country of Origin India																																																				
Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No																																																				
FOR GENERIC DRUG PRODUCTS																																																				
I. Orange Book Rating: <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable																																																				
II. Generic Equivalent to What Brand?: 																																																				
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"/> Yes																																																				
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																																																				
GTIN PRODUCT INFORMATION																																																				
Serialized? <input type="checkbox"/> Yes																																																				
If not, when? 																																																				
Items aggregated? <input type="checkbox"/> Yes																																																				
<table border="1" style="width:100%"><thead><tr><th>Level</th><th>Unit</th><th>Saleable</th><th>Quantity</th><th>GTIN-14</th></tr></thead><tbody><tr><td>Item</td><td>20</td><td>Linear</td><td></td><td></td></tr><tr><td>Box/ Carton/ Bundle/ Inner Pack</td><td>20</td><td>Linear</td><td></td><td></td></tr><tr><td>Case</td><td>20</td><td>Linear</td><td></td><td></td></tr><tr><td>Pallet</td><td>20</td><td>Linear</td><td></td><td></td></tr><tr><td></td><td>20</td><td>Linear</td><td></td><td></td></tr><tr><td></td><td>20</td><td>Linear</td><td></td><td></td></tr><tr><td></td><td>20</td><td>Linear</td><td></td><td></td></tr><tr><td></td><td>20</td><td>Linear</td><td></td><td></td></tr></tbody></table>								Level	Unit	Saleable	Quantity	GTIN-14	Item	20	Linear			Box/ Carton/ Bundle/ Inner Pack	20	Linear			Case	20	Linear			Pallet	20	Linear				20	Linear				20	Linear				20	Linear				20	Linear		
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PHARMACY ORDER / BILL UNIT				ITEM AND PACKING INFORMATION																																																
Rec. sell unit to customer? 				Rx billing unit to pharmacy: 																																																
(Write-in, e.g. 1 Vial)				Each Gram Milliliter																																																
Weight Lbs.				Dimensions (US mmts.)																																																
Depth				Height																																																
Width				Volume (Cups)																																																
# Pieces:																																																				
Item: 0.5				2 4.25 3.25 27.625 1																																																
Box/ Carton/ Bundle/ Inner Pack: 				0																																																
Case: 3				9.5 4.5 6.5 277.875 10																																																
Pallet: 				0																																																
UPC: 																																																				
Case: 																																																				
Carton: 																																																				
COST INFORMATION				WHOLESALE USE ONLY:																																																
Regular Cost \$172.05				Vendor #: 																																																
Invoice Cost (WAC) (\$) \$133.71				Whsl. Code #: 																																																
Federal Excise Tax Per Unit of Sale 				Fineline Code: 																																																
As of date: 9/26/17																																																				
*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: 																																																				