



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date: 2/24/16

PRODUCT INFORMATION				
Company Name:	AvKARE, INC		Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	otc			
Rx Product/Proprietary Name:	Vitamin B6 50mg 50ct Tablet			
NDC:	50268-0858-15	UPC:		
CVX Code:		MXV Code:		
Description:	Vitamin B6 50mg 50ct Tablet			
Active Ingredients:				
URL for Additional Product Information:				
Address:	615 North First Street	Address 2:		
City:	Pulaski	State:	TN	
Key Contact:	Kim Bracey	Email:	kbracey@avkare.com	
Phone Number:	931-908-0028	Fax:	931-292-6229	
Zip:	38478			

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	
II. Brand Name:	
III. Generic Equivalent for Brand:	

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
DUNS:	796580394
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	Yes
If Yes, was original product purchased direct from mfr?	Yes
Is product sold by manufacturer's exclusive distributor?	Yes
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	

ADDITIONAL PRODUCT INFORMATION	
Is the Product...	Direct and Drop Ship
Legend Device?	No
State Control?	No
ARCOS reportable?	No
Co-Licensed?	No
Controlled Substance?	No
Schedule No.?	No
(incl. N for non-narcotic)	
Controlled Substance Code:	
Hazardous Material/Cytotoxic Agent?	No
Is Item...	Unit Dose
If Unit Dose, is item bar coded to unit dose for hospital scanning?	Yes
Is it reverse numbered?	No

ORDER INFORMATION	
Unit of Sale	Bottle
	Box/ Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sgl
	Vial Powder Multi
	Other: Write In
What is the NDC selling unit?	50 pills per box
	10 boxes per case
(Write-in, e.g. 1 Box of 10 Vials)	
Minimum order quantity?	Yes
If Yes, how many of which package type?	
	Each
	Inner/ Carton/ Pack
	Case
	1

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	
(Write-in, e.g. 1 Vial)	
Rx billing unit to pharmacy:	
	Each
	Gram
	Milliliter

Other Product Information	
Size/Strength/Form:	50ct/50mg/ Tablet
Product Shape:	Round
Product Color:	White
Product Imprint:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature - Indicate the USP temperature range for this product.	
I. Freezer - between -25 and -10 C (-13° - 14° F)	☐
II. Cold - between 2 and 8 C (36° - 46° F)	☐
III. Cool - between 8 and 15 C (46° - 59° F)	☐
IV. Controlled Room - between 20 and 25 C (68° - 77° F)	☒
allows for excursions between 15 and 30 C (59° - 86° F)	
V. Avoid Excessive Heat - above 40 C (>104° F)	☐
VI. Other Temperature Range Requirement (write in)	
VII. No Requirement	☐
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?	☐
c. Special regulations for product in certain states?	
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	☐
Protect product (unit of sale) from light?	☐
e. Shelf life:	
Initial shelf life at launch (if different):	
Months	
Months	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Box/ Carton:	0.5	2.00"	4.25"	3.25"		1
Case:	5	9.50"	4.50"	6.50"		10
Pallet:						
UPC:	Case:					
	Carton:					

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
\$14.07	\$11.73	

As of date:	
2/24/16	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.

*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature: _____