



# 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 D3 2000IU 50ct Tablet			
NDC:	50268-0865-15	UPC:		
CVX Code:		MXV Code:		
Description:	Vitamin D3 2000IU 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			

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
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. Contact for temperature excursion questions:	
Name:	
Number:	
Is this product to be shipped to customers on ice?	<input type="checkbox"/>
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/>

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	

ITEM AND PACKING INFORMATION	
c. Special regulations for product in certain states?	
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	<input type="checkbox"/>
Protect product (unit of sale) from light?	<input type="checkbox"/>
e. Shelf life:	
Initial shelf life at launch (if different):	
Months	

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	
<input type="checkbox"/> Bottle	
<input checked="" 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	
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:	
<input type="checkbox"/> Each	
<input type="checkbox"/> Gram	
<input type="checkbox"/> Milliliter	

Other Product Information	
Size/Strength/Form:	50ct/2000IU/ Tablet
Product Shape:	Round
Product Color:	White
Product Imprint:	

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

Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
\$14.77	\$12.31	

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: