© August 2014	Introduction Type: New Item						F	inal Version		Date: 2/24/16				
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name:							a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA, Med Device: OTC							I. Freezer – between -25 and -10 C (-13° – 14° F)							
Rx Product/Proprietary Name: Vitamin D3 5000IU 50ct Tablet							II. Cold – between 2 and 8 C (36° – 46° F)							
NDC: 50268-0866-15 UPC:							III. Cool – between 8 and 15 C (46° – 59° F)							
CVX Code: MVX Code:							x IV. Controlled Room – between 20 and 25 C (68° – 77° F)							
Description: Vitamin D3 5000IU 50ct Tablet							allows for excursions between 15 and 30 C (59° – 86° F) V. Avoid Excessive Heat – above 40 C (>104° F)							
Active ingredients:									erature Range I			1		
URL for Additional Product Information:							VII. No Requirement							
Address: 615 North First Street			Address 2:				b. Contact for temperature excursion questions:							
City:	Pulaski		State:	TN Zip : 38478			Name:							
Key Contact:	Kim Bracey		Email:	kbracey@avkare.com			Number:							
Phone Number:				Fax: 931-292-6229			Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice?							
		FOF	R GENERIC DRUG PRODUC	CTS			is this produ	ct to be snippe	ed to customer	s on ary ice?				
I. Orange Book Rating:			II. Brand Name:				<u> </u>							
III. Generic Equivalent fo							c. Special regu	-				_		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Does supplier meet DSCSA definition of manufacturer? Yes DUNS: 796560394							Special returns requirements for this product?							
Does supplier meet DSCSA definition of manufacturer? Is product exempt from DSCSA? No			Yes DUNS: // 90000394				d. Store product (unit of sale) upright?							
If yes, select exemption:			_				Protect product (unit of sale) from light?					_		
Other exemption - Write in:							i i otobi pi o	auot (aiiit oi o	a.o, og	•		-		
Is product repackaged? Yes If Yes, was original product purchased direct from mfr?						Yes	e. Shelf life:		Months					
Is product sold by manufacturer's exclusive distributor? Yes							or Grion mor	Initial shelf I	ife at launch (i	f different):		Months		
Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA												-		
ADDITIONAL PRODUCT INFORMATION								ITEM AND	PACKING INF	ORMATION				
Is the Product Direct and Drop Ship		ORDER INFORMATION				Dimensions (US memts.) Volume					" D:			
Legend Device?		No	Unit of Sale	What is the N	IDC selling unit?		Weight Lbs.	Depth	Height	Width:	(Cube)	# Pieces:		
State Control?		No	Bottle	50 pills per bo	ox	Item:	0.5	2.00"	4.25"	3.25"		1		
ARCOS reportable?		No	x Box/Carton	10 boxes per			0.0	2.00	20	0.20				
Co-Licensed? Controlled Substance?		No No	Ampule Glass	(Write-in, e.g	. 1 Box of 10 Vials)	Box/								
Schedule No.?		INO	Tube	Minimum ord	er quantity? Yes	Carton:								
(incl. N for non-narcot	4i a\			William Or C	er quaritity: 165				4.50"	6.50"		10		
			Vial Liquid Sgl			Case:	5	9.50"	4.50	0.00				
Controlled Substance Co Hazardous Material/Cyto	ode:	No	Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	If Yes, how n	nany of which package type? Each	Case:	5	9.50"	4.50	0.50				
Controlled Substance Co Hazardous Material/Cyto	ode: otoxic Agent?	No	Vial Liquid Multi Vial Powder Sql Vial Power Multi	If Yes, how n	Each Inner/Carton/Pack	Pallet:	Case:	9.50"	4.30	0.50				
Controlled Substance Co Hazardous Material/Cyto Is Item	ode: otoxic Agent? Unit Dose	No	Vial Liquid Multi Vial Powder Sql	If Yes, how n	Each			9.50"	4.30	0.00				
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co	ode: otoxic Agent? Unit Dose		Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	1	Each Inner/Carton/Pack Case	Pallet: UPC:	Case:	9.50"						
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning?	ode: otoxic Agent? Unit Dose coded to unit dose for	Yes	Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER	1 / BILL UNIT	Each Inner/Carton/Pack Case Other Product Informati	Pallet: UPC:	Case: Carton:		COST INFO					
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co	ode: otoxic Agent? Unit Dose coded to unit dose for		Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	1 / BILL UNIT	Each Inner/Carton/Pack Case Other Product Informati Size/Strength/Form:	Pallet: UPC:	Case: Carton:	Per Unit of	COST INFO			cise Tax Per		
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning? Is it reverse numbered?	ode: toxic Agent? Unit Dose coded to unit dose for	Yes	Vial Liquid Multi Vial Powder Sql Vial Powder Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor	1 / BILL UNIT	Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 50ct/50001U/Tablet	Pallet: UPC:	Case: Carton:	Per Unit of	COST INFO	DRMATION		cise Tax Per		
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning? Is it reverse numbered?	ode: otoxic Agent? Unit Dose coded to unit dose for	Yes	Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g.	/ BILL UNIT	Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 50ct/5000IU/Tablet Product Shape: Round	Pallet: UPC:	Case: Carton:	Per Unit of	COST INFO	DRMATION Dest (WAC) (\$)				
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning? Is it reverse numbered? WHOLE! Vendor #:	ode: toxic Agent? Unit Dose coded to unit dose for	Yes	Vial Liquid Multi Vial Powder Sql Vial Powder Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn	/ BILL UNIT	Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 50ct/50001U/Tablet	Pallet: UPC:	Case: Carton:	Per Unit of	COST INFO	DRMATION				
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning? Is it reverse numbered?	ode: toxic Agent? Unit Dose coded to unit dose for	Yes	Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g.	/ BILL UNIT	Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 50ct/5000IU/Tablet Product Shape: Round	Pallet: UPC:	Case: Carton:	Per Unit of	COST INFO	DRMATION Dest (WAC) (\$)				
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning? Is it reverse numbered? WHOLE! Vendor #:	ode: toxic Agent? Unit Dose coded to unit dose for	Yes	Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn Each	/ BILL UNIT	Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 50ct/5000IU/Tablet Product Shape: Product Color: White	Pallet: UPC:	Case: Carton:	Per Unit of	COST INFO	DRMATION Dest (WAC) (\$)				
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning? Is it reverse numbered? WHOLE! Vendor #:	ode: toxic Agent? Unit Dose coded to unit dose for SALER USE ONLY:	Yes No	Vial Liquid Multi Vial Power Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharm Each Gram Milliliter	/ BILL UNIT ner? 1 Vial)	Each Inner/Carton/Pack Case Other Product Informati Size/Strength/Form: [Soct/5000IU/Tablet Product Shape: Product Shape: Product Imprint:	Pallet: UPC:	Case: Carton:	Per Unit of (\$)	COST INFO Invoice Co \$: As of date:	DRMATION Uset (WAC) (\$)				
Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning? Is it reverse numbered? WHOLE! Vendor #:	ode: Unit Dose Unit dose for SALER USE ONLY:	Yes No	Vial Liquid Multi Vial Power Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharm Each Gram Milliliter	1 Vial) hacy:	Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 50ct/5000IU/Tablet Product Shape: Product Color: White	Pallet: UPC:	Case: Carton:	Per Unit of (\$)	COST INFO Invoice Co \$: As of date:	DRMATION Uset (WAC) (\$)				