© August 2014	Introduction Type: New Item							Final Version		Date:	7/2	5/16	
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Company Name: AvKARE, INC Application: ANDA						DA	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA, Med Device: 4112					•			I. Freezer - bet	ween -25 and -	10 C (-13° - 14°	F)		
Rx Product/Proprietary Name: Vitamin D3 5000 IU Softgels 50ct						II. Cold – between 2 and 8 C (36° – 46° F)							
NDC:	50268-0868-15			UPC:				III. Cool - between	een 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 5000 IU S	Softgels 50ct					allows for excursions between 15 and 30 C (59° – 86° F) V. Avoid Excessive Heat – above 40 C (>104° F)						
Active ingredients:								VI. Other Tempe			'',	,	
URL for Additional Product Information:							(write in) VII. No Requirement						
Address: 615 North First Street			Address 2:				b. Contact for temperature excursion questions:						
City:	Pulaski		State:	State: TN Zip: 38478			Name:						
Key Contact:	Kim Bracey		Email:	kbracey@avk			Number:						
Phone Number:	931-908-0028		Fax:	931-292-6229	1			luct to be shippe				_	
		FOR	GENERIC DRUG PRODUC	CTS			Is this prod	luct to be shippe	ed to customer	s on dry ice?			
I. Orange Book Rating:			II. Brand Name:				<u></u>						
III. Generic Equivalent fo							1 '	gulations for pr				_	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						1	Special retu	urns requiremen	ts for this prod	uct?			
Does supplier meet DSCSA definition of manufacturer?			Yes DUNS: 796560394				d Store mee	duct funit of cal	a)				
Is product exempt from DSCSA? No							d. Store product (unit of sale) upright? Protect product (unit of sale) from light?					_	
If yes, select exemption: Other exemption - Write in:							Protect pr	oduct (unit of s	are) from right	r		_	
	te III.		If Very war and all and an advert assemble and all and form an fig.				e. Shelf life:		Months				
Is product repackaged? Yes If Yes, was original product purchased direct to Is product sold by manufacturer's exclusive distributor? Yes					nased direct from mir?	Yes	e. Shelf life:	Initial shalf I	Nonths life at launch (if different):		Months	
Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA													
ADDITIONAL PRODUCT INFORMATION													
	Tior product ib/barcoc				documentation from FDA			ITEM AND	PACKING INF	ORMATION			
Is the Product		ADDITIONAL		,					PACKING INF		Volume		
Is the Product	Direct and Drop Ship	ADDITIONAL		ORDER INFOR	RMATION		Weight Lbs.	Dim	nensions (US n	nsmts.)	Volume (Cube)	# Pieces:	
Is the Product Legend Device? State Control?		ADDITIONAL	PRODUCT INFORMATION	ORDER INFOR	RMATION IDC selling unit?	Itomi		Dim Depth	nensions (US n Height	nsmts.) Width:	Volume (Cube)		
Legend Device? State Control? ARCOS reportable?		No No No	PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton	ORDER INFOR What is the N	RMATION IDC selling unit? apsules	Item:	Weight Lbs.	Dim	nensions (US n	nsmts.)		# Pieces:	
Legend Device? State Control? ARCOS reportable? Co-Licensed?		No No No No	Unit of Sale Bottle X Box/Carton Ampule	ORDER INFOR What is the N	RMATION IDC selling unit?	Box/		Dim Depth	nensions (US n Height	nsmts.) Width:			
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?		No No No	Unit of Sale Bottle Box/Carton Ampule Glass	ORDER INFOR What is the N 1 box of 50 ci (Write-in, e.g	EMATION IDC selling unit? apsules 1. 1 Box of 10 Vials)			Dim Depth	nensions (US n Height	nsmts.) Width:			
Legend Device? State Control? ARCOS reportable? Co-Licensed?	Direct and Drop Ship	No No No No	PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube	ORDER INFOR What is the N	EMATION IDC selling unit? apsules 1. 1 Box of 10 Vials)	Box/		Dim Depth	nensions (US n Height	nsmts.) Width:			
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cor	Direct and Drop Ship	No No No No No No	Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N 1 box of 50 c (Write-in, e.g	MATION IDC selling unit? apsules 1. 1 Box of 10 Vials) Ider quantity? Yes The property of	Box/ Carton: Case:	0.5	Dim Depth 2.00"	nensions (US n Height 4.25"	nsmts.) Width: 3.25"		1	
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct and Drop Ship	No No No No	Unit of Sale Bottle Bottle Sox/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	ORDER INFOR What is the N 1 box of 50 c (Write-in, e.g	MATION IDC selling unit? apsules 1. 1 Box of 10 Vials) Ider quantity? Yes Inany of which package type? Each	Box/ Carton:	0.5	Dim Depth 2.00"	nensions (US n Height 4.25"	nsmts.) Width: 3.25"		1	
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cor Hazardous Material/Cytol	Direct and Drop Ship Lich de: Loxic Agent?	No No No No No No	PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Power Multi Vial Power Multi	ORDER INFOR What is the N 1 box of 50 c (Write-in, e.g	MATION MDC selling unit? apsules 1. 1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack	Box/ Carton: Case:	0.5 5	Dim Depth 2.00"	nensions (US n Height 4.25"	nsmts.) Width: 3.25"		1	
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Coo Hazardous Material/Cytot Is Item	Direct and Drop Ship Lic) de: toxic Agent? Unit Dose	No No No No No No	Unit of Sale Bottle Bottle Sox/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	ORDER INFOR What is the N 1 box of 50 c (Write-in, e.g	MATION IDC selling unit? apsules 1. 1 Box of 10 Vials) Ider quantity? Yes Inany of which package type? Each	Box/ Carton: Case: Pallet:	0.5	Dim Depth 2.00"	nensions (US n Height 4.25"	nsmts.) Width: 3.25"		1	
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