© August 2014		Introduction Type: New Item					inal Version		Date:	2/2	3/16	
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Company Name: AvKARE, INC Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/B	LA, Med Device:	OTC					. Freezer – betv	ween -25 and -	10 C (-13° - 14°	F)		
Rx Product/Proprietary Name: Calcium Carbonate Chewable 500mg Tablet 30ct						II. Cold – between 2 and 8 C (36° – 46° F)						
NDC: 50268-0149-	3		UPC:				 Cool – between 	en 8 and 15 C	(46° - 59° F)			
CVX Code: MVX Code:						x I			20 and 25 C (6			
Description: Calcium Carbonate Chewable 500mg Tablet 30ct									en 15 and 30 C			
Active ingredients:						V. Avoid Excessive Heat – above 40 C (>104° F) VI. Other Temperature Range Requirement						
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:	TN	Zip: 38478		Name:						
Key Contact: Kim Bracey		Email:	kbracey@avka	are.com		Number:						
Phone Number: 931-908-0028		Fax:	931-292-6229				uct to be shippe					
	FOI	R GENERIC DRUG PRODUC	CTS			Is this produ	uct to be shippe	ea to customer	s on dry ice?			
I. Orange Book Rating: NA		II. Brand Name: onate Chewable	NA									
III. Generic Equivalent for Brand:			c. Special reg	ulations for pro	oduct in certai	n states?						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						Special retu	rns requirement	s for this prod	uct?			
Does supplier meet DSCSA definition of manufacturer? Yes DUNS: 796560394								-)!1-40				
Is product exempt from DSCSA?	_				d. Store product (unit of sale) upright? Protect product (unit of sale) from light?							
If yes, select exemption:					Protect pro	oduct (unit of s	ale) from light	?				
Other exemption - Write in:												
Is product repackaged? Yes If Yes, was original product purchased direct from Is product sold by manufacturer's exclusive distributor? Yes					Yes	e. Shelf life:	1-141-1 -1-141	Months			Months	
Is product sold by manufacturer's exclusive distributor? Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA							initiai sneiti	ife at launch (i	it different):		Wonths	
AZE any waivers granted for product ID/barcode? NO IT yes, attach documentation from FDA ADDITIONAL PRODUCT INFORMATION							ITEM AND	DACKING INE	ODMATION			
Is the Product Direct and Drop Ship			ORDER INFORMATION			Dimensions (US msmts.) Volume						
Legend Device?						Weight Lbs.		ensions (os n			" -	
		Unit of Sale	What is the N	DC selling unit?			Donth	Height	Width:	(Cubo)	# Pieces:	
State Control?	No No	Unit of Sale	What is the Ni				Depth	Height	Width:	(Cube)		
State Control? ARCOS reportable?	No No No	Bottle x Box/Carton	30 pills per bo	x	Item:	0.3	2.00"	Height 4.25"	Width: 3.25"	(Cube)	# Pieces:	
	No	Bottle	30 pills per box 10 boxes per o	x	Item:	0.3				(Cube)		
ARCOS reportable? Co-Licensed? Controlled Substance?	No No	Bottle x Box/Carton Ampule Glass	30 pills per bo 10 boxes per o (Write-in, e.g.	x case 1 Box of 10 Vials)		0.3				(Cube)		
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	No No No	Bottle x Box/Carton Ampule Glass Tube	30 pills per box 10 boxes per o	x case 1 Box of 10 Vials)	Box/	0.3				(Cube)		
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic)	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl	30 pills per bo 10 boxes per c (Write-in, e.g.	x case 1 Box of 10 Vials) er quantity? Yes	Box/ Carton:		2.00"	4.25"	3.25"	(Cube)	1	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code:	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	30 pills per bo 10 boxes per c (Write-in, e.g.	x	Box/ Carton:		2.00"	4.25"	3.25"	(Cube)	1	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic)	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl	30 pills per bo 10 boxes per c (Write-in, e.g.	x case 1 Box of 10 Vials) er quantity? Yes	Box/ Carton: Case: Pallet:		2.00"	4.25"	3.25"	(Cube)	1	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code:	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	30 pills per bo 10 boxes per c (Write-in, e.g.	x asse 1 Box of 10 Vials) er quantity? Yes any of which package type? Each	Box/ Carton: Case:	3	2.00"	4.25"	3.25"	(Cube)	1	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent?	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	30 pills per bo 10 boxes per c (Write-in, e.g.	x 2389 1 Box of 10 Vials) er quantity? Yes any of which package type? Each Inner/Carton/Pack	Box/ Carton: Case: Pallet:	3 Case:	2.00"	4.25"	3.25"	(Cube)	1	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	30 pills per bo. 10 boxes per c (Write-in, e.g. Minimum orde If Yes, how m	x 2389 1 Box of 10 Vials) er quantity? Yes any of which package type? Each Inner/Carton/Pack	Box/ Carton: Case: Pallet: UPC:	3 Case:	2.00"	4.25"	3.25"	(Cube)	1	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is item bar coded to unit de	No No No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	30 pills per bo. 10 boxes per s (Write-in, e.g. Minimum orde If Yes, how m	x	Box/ Carton: Case: Pallet: UPC:	3 Case: Carton:	2.00"	4.25" 4.50"	3.25" 6.50"	(Cube)	10	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is item bar coded to unit do hospital scanning? Is it reverse numbered?	No N	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor	30 pills per bo 10 boxes per s (Write-in, e.g. Minimum orde If Yes, how m 1	x case 1 Box of 10 Vials) er quantity? Yes any of which package type? Each Inner/Carton/Pack Case Other Product Informat	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.00" 9.50"	4.25" 4.50"	3.25"		1 10 ise Tax Per	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is item bar coded to unit do hospital scanning?	No N	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Wite-in, e.g.	30 pills per bo. 10 boxes per v. (Write-in, e.g., Minimum orde If Yes, how m 1 BILL UNIT ner? 1 Vial)	x	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.00" 9.50" t Per Unit of e (\$)	4.50" 4.50" COST INFO	3.25" 6.50" ORMATION DIST (WAC) (\$)	Federal Exc	1 10 ise Tax Per	
ARCOS reportable? Co-Licensed? Cotrolled Substance? Schedule No.? (Incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is item bar coded to unit do hospital scanning? Is it reverse numbered? WHOLESALER USE OF	No N	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl 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 pharm	30 pills per bo. 10 boxes per v. (Write-in, e.g., Minimum orde If Yes, how m 1 BILL UNIT ner? 1 Vial)	x 2858 1 Box of 10 Vials) or quantity? Yes any of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30ct/500mg/Tablet	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.00" 9.50" t Per Unit of e (\$)	4.50" 4.50" COST INFO	3.25" 6.50"	Federal Exc	1 10 ise Tax Per	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is Item bar coded to unit do hospital scanning? Is it reverse numbered? WHOLESALER USE OF WHOLESALER USE OF	No N	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl 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	30 pills per bo. 10 boxes per v. (Write-in, e.g., Minimum orde If Yes, how m 1 BILL UNIT ner? 1 Vial)	x ase 1 Box of 10 Vials) or quantity? Yes any of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30ct/500mg/Tablet Product Shape: Product Color: white	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.00" 9.50" t Per Unit of e (\$)	4.50" 4.50" COST INFO	3.25" 6.50" ORMATION DIST (WAC) (\$)	Federal Exc	1 10 ise Tax Per	
ARCOS reportable? Co-Licensed? Cotrolled Substance? Schedule No.? (Incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is item bar coded to unit do hospital scanning? Is it reverse numbered? WHOLESALER USE OF	No N	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn Each Gram	30 pills per bo. 10 boxes per v. (Write-in, e.g., Minimum orde If Yes, how m 1 BILL UNIT ner? 1 Vial)	A Case 1 Box of 10 Vials) or quantity? Yes any of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30oct/500mg/Tablet Product Shape: round	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.00" 9.50" t Per Unit of e (\$)	4.25" 4.50" COST INFO Invoice Co	3.25" 6.50" 0RMATION 0st (WAC) (\$) 6.86	Federal Exc	1 10 ise Tax Per	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is Item bar coded to unit do hospital scanning? Is it reverse numbered? WHOLESALER USE OF WHOLESALER USE OF	No N	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ONDER Rec. sell unit to custor (Wite-in, e.g. Rx billing unit to pharm Each Gram Milliliter	30 pills per bo. 10 boxes per st. (Write-in, e.g., e.g	A CASS CASS CASS CASS CASS CASS CASS CA	Box/ Carton: Case: Pallet: UPC:	Case: Carton: Regular Cos Sale	2.00° 9.50° t Per Unit of e (\$)	4.25" 4.50" COST INFO Invoice Co	3.25" 6.50" ORMATION DIST (WAC) (\$)	Federal Exc	1 10 ise Tax Per	
ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is Item bar coded to unit do hospital scanning? Is it reverse numbered? WHOLESALER USE OF WHOLESALER USE OF	No N	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ONDER Rec. sell unit to custor (Wite-in, e.g. Rx billing unit to pharm Each Gram Milliliter	30 pills per bo. 10 boxes per s (Wife-in, e.g. Minimum orde If Yes, how m 1 BILL UNIT ner? 1 Vial) nacy:	x ase 1 Box of 10 Vials) or quantity? Yes any of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30ct/500mg/Tablet Product Shape: Product Color: white	Box/ Carton: Case: Pallet: UPC:	Case: Carton: Regular Cos Sale	2.00° 9.50° t Per Unit of e (\$)	4.25" 4.50" COST INFO Invoice Co	3.25" 6.50" 0RMATION 0st (WAC) (\$) 6.86	Federal Exc	1 10 ise Tax Per	