© August 2014			Intro	duction Type:	New Item		F	inal Version		Date:			
PRODUCT INFORMATION								SPECIAL HAI	NDLING AND S	TORAGE REQU	IREMENTS*		
Company Name:	AvKARE, INC		Application: AND			ANDA	a. Temperature – Indicate the USP temperature range for this product.						
Application Number fo	nDA/ANDA/BLA, Me	ed Device:	201504				I. Freezer – between -25 and -10 C (-13° – 14° F)						
			marate 300mg Tablet UD50				II. Cold – between 2 and 8 C (36° – 46° F)						
NDC:	50268-0634-15		<b>,</b>	UPC:				II. Cool - between					
CVX Code:			MVX Code:				x IV. Controlled Room – between 20 and 25 C (68° – 77° F)						
Description:	Quetiapine Fumarate	e 300mg Tablet U	ID50				allows for excursions between 15 and 30 C (59° – 86° F)  V. Avoid Excessive Heat – above 40 C (>104° F)						
Active ingredients:								/I. Other Tempe			F)	7	
URL for Additional Produ	ct Information:							(write in) /II. No Require	nent			]	
Address: 615 North First Street			Address 2:				b. Contact for temperature excursion questions:						
City:	Pulaski		State:				Name:						
Key Contact:	Kim Bracey		Email:	kbracey@avk	care.com		Number:						
Phone Number: 931-908-0028			Fax:	931-292-6229	1	Is this product to b			hipped to customers on ice?				
		FOR	GENERIC DRUG PRODUC	CTS			Is this produ	uct to be shippe	ed to customer:	s on dry ice?			
I. Orange Book Rating:	AB		II. Brand Name:	Seroquel								=	
III. Generic Equivalent for Brand: Quetiapine Fu							c. Special reg	ulations for pr	oduct in certai	n states?			
	DR	RUG SUPPLY CH	AIN SECURITY ACT (DSCSA) INFORMATION				Special retu	rns requiremen	ts for this prod	uct?			
Does supplier meet DSCSA definition of manufacturer?			Yes DUNS: 796560394										
Is product exempt from DSCSA? No			_				d. Store prod	uct (unit of sal	e) upright?			_	
If yes, select exemption							Protect pro	oduct (unit of s	ale) from light	?			
Other exemption - Wri	te in:												
Is product repackaged? Yes			If Yes, was original product purchased direct from mfr?										
				iai product purc	hased direct from mfr?	Yes	e. Shelf life:		Months				
Is product sold by manuf		distributor?	Yes			Yes	e. Shelf life:	Initial shelf	Months ife at launch (	f different):		Months	
		distributor? de?	Yes No		hased direct from mfr?	Yes	e. Shelf life:		ife at launch (	,		Months	
Is product sold by manuf Are any waivers granted	for product ID/barco	distributor? de? ADDITIONAL	Yes	If yes, attach	documentation from FDA	Yes	e. Shelf life:	ITEM AND	ife at launch (	ORMATION		Months	
Is product sold by manuf- Are any waivers granted  Is the Product		distributor? de? ADDITIONAL	Yes No PRODUCT INFORMATION	If yes, attach	documentation from FDA	Yes		ITEM AND	PACKING INF	ORMATION ismts.)	Volume	Months # Pieces:	
Is product sold by manuf Are any waivers granted Is the Product Legend Device?	for product ID/barco	distributor? de? ADDITIONAL p No	Yes No PRODUCT INFORMATION Unit of Sale	ORDER INFOR	a documentation from FDA	Yes	e. Shelf life:  Weight Lbs.	ITEM AND	ife at launch (	ORMATION	Volume (Cube)		
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