



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

☒ Final Version

Date: 6/10/15

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name: <input type="text"/> AvKARE, Inc Application: <input type="text"/> ANDA		a. Temperature – Indicate the USP temperature range for this product.	
Application Number for NDA/ANDA/BLA, Med Device: <input type="text"/> 40885		<input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F)	
Rx Product/Proprietary Name: <input type="text"/> Butalbital, Acetaminophen and Caffeine 50/300/40mg Capsule		<input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F)	
NDC: <input type="text"/> 42291-0181-01 UPC: <input type="text"/>		<input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F)	
CVX Code: <input type="text"/> MVX Code: <input type="text"/>		<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)	
Description: <input type="text"/> Butalbital, Acetaminophen and Caffeine 50/300/40mg Capsule		<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)	
Active Ingredients: <input type="text"/>		<input type="checkbox"/> VI. Other Temperature Range Requirement (write in) <input type="text"/>	
URL for Additional Product Information: <input type="text"/>		<input type="checkbox"/> VII. No Requirement	
Address: <input type="text"/> 615 North First Street Address 2: <input type="text"/>		b. Contact for temperature excursion questions:	
City: <input type="text"/> Pulaski State: <input type="text"/> TN Zip: <input type="text"/> 38478		Name: <input type="text"/>	
Key Contact: <input type="text"/> Kim Bracey Email: <input type="text"/> kbracey@avkare.com		Number: <input type="text"/>	
Phone Number: <input type="text"/> 931-908-0028 Fax: <input type="text"/> 931-292-6229		Is this product to be shipped to customers on ice? <input type="text"/>	
FOR GENERIC DRUG PRODUCTS		Is this product to be shipped to customers on dry ice? <input type="text"/>	
I. Orange Book Rating: <input type="text"/> AB II. Brand Name: <input type="text"/> Fioricet®		c. Special regulations for product in certain states?	
III. Generic Equivalent for Brand: <input type="text"/> Butalbital, Acetaminophen and Caffeine		Special returns requirements for this product? <input type="text"/>	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION		d. Store product (unit of sale) upright?	
Does supplier meet DSCSA definition of manufacturer? <input type="text"/> No DUNS: <input type="text"/> 796560394		Protect product (unit of sale) from light? <input type="text"/>	
Is product exempt from DSCSA? <input type="text"/> No		e. Shelf life: <input type="text"/> Months	
If yes, select exemption: <input type="text"/>		Initial shelf life at launch (if different): <input type="text"/> Months	
Other exemption - Write in: <input type="text"/>			
Is product repackaged? <input type="text"/> Yes If Yes, was original product purchased direct from mfr? <input type="text"/> Yes			
Is product sold by manufacturer's exclusive distributor? <input type="text"/> Yes			
Are any waivers granted for product ID/barcode? <input type="text"/> No If yes, attach documentation from FDA			
ADDITIONAL PRODUCT INFORMATION		ITEM AND PACKING INFORMATION	
Is the Product... <input type="text"/> Direct and Drop Ship		Weight Lbs. <input type="text"/> 92.33g Dimensions (US msmts.) <input type="text"/> 4.25" <input type="text"/> 4.50" <input type="text"/> 2.20" Volume (Cube) <input type="text"/> # Pieces: <input type="text"/>	
Legend Device? <input type="text"/> No		Item: <input type="text"/>	
State Control? <input type="text"/> No		Box/ Carton: <input type="text"/>	
ARCOS reportable? <input type="text"/> No		Case: <input type="text"/>	
Co-Licensed? <input type="text"/> No		Pallet: <input type="text"/>	
Controlled Substance? <input type="text"/> No		UPC: <input type="text"/>	
Schedule No.? <input type="text"/>		Case: <input type="text"/>	
(incl. N for non-narcotic)		Carton: <input type="text"/>	
Controlled Substance Code: <input type="text"/>			
Hazardous Material/Cytotoxic Agent? <input type="text"/> No			
Is Item... <input type="text"/>			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>			
Is it reverse numbered? <input type="text"/>			
WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT	
Vendor #: <input type="text"/>		Rec. sell unit to customer? <input type="text"/>	
Whsl. Code #: <input type="text"/>		Size/Strength/Form: <input type="text"/> 100ct/50-300-40mg/Capsule	
Fineline Code: <input type="text"/>		Product Shape: <input type="text"/> capsule	
		Product Color: <input type="text"/> light blue opaque	
		Product Imprint: <input type="text"/> cap is imprinted twice with "Fioricet" in black	
		Rx billing unit to pharmacy: <input type="text"/>	
		Regular Cost Per Unit of Sale (\$) <input type="text"/> \$304.87 Invoice Cost (WAC) (\$) <input type="text"/> \$243.90 Federal Excise Tax Per Unit of Sale <input type="text"/>	
		As of date: <input type="text"/> 6/10/15	
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: <input type="text"/>			