

# **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

Version 2021						Introduction Type:	New Item		x Final Version			Date:	6/1/	2022
			PRODUCT INFORMA	TION					SPECIAL HAI	NDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:														
DUNS:	82-677-4775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Famo	otidine Tablets USP, 40mg 10						(write in)					
Selling Unit NDC:	31722-018-10		Unit of Use NDC:				722018104		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Oral Solid - Table	t, Round Shaped, W	/hite,'12' and 'T'						Is this product to be shippe	d to customers on i	ce?		No	
									Is this product to be shippe	d to customers on o	dry ice?		No	
Active Ingredient(s): Famotidine														
NO. C. A. Miller of Dr. And A. C. Company							b. Contact fo	or temperature excursion qu	estions:					
URL for Additional Product Inforn		h (I) 000 0	and the Arman Coultry A			A ddunan O.		-	Name:		Soma Raju	20		
Address: City:	Piscataway	Ave (and) 800 Cente	enniai Ave, Suite 1		State:	Address 2:	o: 08854	-	Number: Group E-mail:		732-529-042	23 @heterousa	. com	
Key Contact:	Customer Service	<b>.</b>			Email:		camberpharma.com	-	Group E-mail.		Sumaraju	<u>wheterous</u>	a.com	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	camber pharma.com	c. Special re	gulations for product in any	states?			No	1
Product Therapeutic Classificatio									Special returns requiremen				No	
l round morapound diagonicans	•••								opoolal rotatrio roquitorilor	no for ano product.			110	
	ADDITI	ONAL PRODUCT II	NFORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store prod	d. Store product (unit of sale) upright?					1
The product is?			Is the Product	Direct-Ship Onl	v			11	Protect product (unit of s	ala) from light?			No	1
a legend device?		No	Is the Product	Neither	,		1000ct	e. Shelf life:	Protect product (unit of s	ale) Irom ngmr			24	Months
if yes, enter class #		140	Orphan Drug Status	1141111		Size:	100001	C. Onen me.	Initial shelf life at launch	(if different):			2.7	Months
a product kit?		No	orpilari Drug otatao			a	40mg		minus onon mo ut luunon	( ao. o).				
if yes, list NDCs of			FDA Approval Status			Strength:	9			ORDER INFORM	MATION			
component parts						Dosage Form:	Oral Solid - Tablet							
reverse numbered?		No				Dosage i oiii.			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 1			
latex-free?		Yes				Product Shape:	Round		Box/Carton		(Write-in, e.	.g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes					White		Ampule Glass		Minimum			Vaa
opioid?		No No				Product Color:	vvriite		Tube		winimum o	rder quantity	,,	Yes
Cannabinoid?		No	Country of Origin	India			'12' and 'T'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		,g			Product Imprint:			Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
hospital scanning?		No	Is this product covered to	under the					Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	lo				Vial Power Multi			Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Au		Authorized Generic, other			HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sec	tion fields are not applicable	Rec. sell uni	t to customer?	_	Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	ınd?:	Pepcid										Each		
		DDIIC CUDE	PLY CHAIN SECURITY ACT	(Dece A) INFORM	ATION			(Write-in, e.g	j. 1 Vial)			Gram		
		DRUG SUFF	LI CHAIN SECURITI ACT	(D3C3A) INFORM	ATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	rer?	Yes		LN:	0331722000000			ITE	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No			0001122000000						•		
If ves. select exemption:					CP:			-		Dimensi	ions (US msr	nte \	Volume	Saleable #
Other exemption - Write in:								_	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	If	ves. was or	riginal product purchase	ed	Item/Each:		Берин	1			
Is product sold by manufacturer's	exclusive distribu	itor?	Yes		irect from m				0.55		2.5	5	0	1
Has FDA granted waiver/exceptio	n/exemption for pr	oduct?	No	P	rovide sour	ce manufacturer for rep	ackaged product	Box/Carton/	Bundle/				0	
If yes, attach documentation from	m FDA.							Inner Pack:					0	
								Case:	6.89	12	9.25	7.5	0	12
		G1	IN AND HIBCC PRODUCT I	NFORMATION										
Saleable Unit of Measure					0.711			Pallet:					0	
	S	Saleable Quantity	HIBCC			N-14 31722018104	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		-			003	31722018104			COST INFORMATION			WHOLESAL	FR USF ON	γ
X Case		12			203:	31722018108			- COOT IN ORMATION			OLILOAL	LIN OOL ON	
Pallet					200			Regular Cos	t		Vendor #:			
								Invoice Cost		\$15.00	Whsl. Code	#:		
											Fineline Co			
								As of date:						
								11						
μ								Щ			<u> </u>			
		_	Attach copy of SAFETY D	ATA SHEET (SDS)	or non haza		ERT, LABEL AND PHOTO OF	PRODUCT PACK						
*Please provide any additional inf	formation on page	2.				See new p. 3 for Desi	gnated Drop Ship Only.		Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic?	SDS Hazard Classification					
<ul> <li>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?</li> <li>Is the product a CA Prop 65 carcinogen?</li> <li>Is the product a CA Prop 65 reproductive toxicant?</li> <li>Does the product label bear a CA Prop 65 warning?</li> </ul>	X Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
c. Contact Hazard?      d. Does this product require special clean-up instructions?         (If yes, attach SDS with special instructions.)      e. Does the product contain DEHP?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:					
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class		Hazardous Waste Identification				
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA?	No		· · · · · · · · · · · · · · · · · · ·			
(if yes, answer a-e below and provide SDS) a. UN/Identification Number		REMS of	r REGISTRY RESTRICTIONS			
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No			
Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit?  (if yes, identify method below)  Limited Quantity  Consumer Commodity, ORM-D  Small Quantity (49 CFR 173.4)		REMS:  REMS Program Manager Name:  Supplier Manages REMS registry exclusively:  Wholesale distributor support:  Provider Name:  Site Enrollment Number assigned by Supplier:	No	Phone:  DEA #: NCPDP#: NPI #:		
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments				
SP#		Registry:	No			
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:		
Is the Product  Controlled Substance?  No Controlled Substance Code		R	ETURN INSTRUCTIONS			
Controlled by State(s)? ARCOS Reportable? Schedule No.  No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged:  Is product returnable for credit:	1-866-827-3647 Yes			
CLASS OF TRADE RESTRICTION:	Yes	URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:	No No	Special regulations or returns requirements for this product in certain states?				
Restricted from US territories? (explain in comments)  Comments:	If so, which states? Other requirements? Comments?					
M	SCELLANEC	OUS NOTES and/or Image of Product Barcode:				



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#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing				
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:				
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:				
Expedited Freight Charges or Other Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  PO Receipt cut off time:				
Drop Ship miscellaneous fees billed:  Comments:		Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday				
		Priority Overnight receipt available:				
Class of Trade Restriction		PO Receipt Cut off time:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:				
Other Data Information Required to F	rocess PO:	Return Instructions				
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged:  Is product returnable for credit:  URL/Link to returns policy:  Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?				
Miscellaneous Notes:						
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				