

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 HAN	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application:	ANDA	a. Temperati	ure - Indicate the USP temp	erature range for t	this product.			
Application Number for NDA/AN	IDA/BLA (drug); PN	IA/510(k)(med devi	ice):	215	767		<u> </u>		Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica			·						-					
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:		1						
Description:	Oral Solid - Tablet	, Round Shaped, W	/hite,'12' and 'T'					T	Is this product to be shippe	d to customers on i	ice?		No	
									Is this product to be shippe	d to customers on	dry ice?		No	
Active Ingredient(s):		Famotidine												
								b. Contact fo	or temperature excursion qu	estions:				
URL for Additional Product Inform Address:		(aad) 000 Caata	anial Arra Crrita 4			Address 2:		+	Name:		Soma Raju	22		
City:	Piscataway	ve (and) 800 Cente	enniai Ave, Suite 1		State:		o: 08854	-	Number: Group E-mail:		732-529-042	23 @heterous:	. com	
Key Contact:	Customer Service				Email:		camberpharma.com	-	Group E-mail.		SUITIALAJU	<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 Classification									Special returns requiremen				No	
l round morapound diagonicum	•••								opoolar rotarrio roquirorriorr	to for the product.			- 110	
	ADDITIO	ONAL PRODUCT IN	NFORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship Or	nlv				Protect product (unit of sa	ale) from light?			No	1
a legend device?		No	Is the Product	Neither	y		1000ct	e. Shelf life:	Protect product (unit of Se	ale) Irom light?			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	100000	c. onen me.	Initial shelf life at launch (if different):			2.7	Months
a product kit?		No					40mg			, , .				
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFOR	MATION			
component parts						Dosage Form:	Oral Solid - Tablet							
reverse numbered?		No				Dosage Form.			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?		Yes				•	NATE:		Ampule				.0	
correctional institution block? opioid?		No No				Product Color:	White		Glass Tube		Minimum o	rder quantity	/?	Yes
Cannabinoid?		No	Country of Origin	India			'12' and 'T'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	140	Country of Origin	IIIdia		Product Imprint:	12 dild 1		Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?	ann 4000 101	No	Is this product covered u	under the					Vial Powder Sql			Each	p	-51
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Power Multi			Inner/Cartor	n/Pack	
			_						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
											_			
					Au		Authorized Generic, other		Pł	HARMACY ORDER	R / 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	acy:	
II. Generic Equivalent to What Bra	ınd?:	Pepcid										Each		
								(Write-in, e.g	ı. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFORI	MATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	or?	Yes	_	GLN:	0331722000000			ITEN	M AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?	ition of manufactur	GI:	No	_	GLIV.	0331722000000				I AND I AGINING I	IN OKMATIO			
If ves. select exemption:			***		GCP:					Dimens	ions (US msr	nte \	Volume	Saleable #
Other exemption - Write in:					GCP:			_	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes was or	riginal product purchas	he	Item/Each:		Deptii				
Is product sold by manufacturer's	exclusive distribu	tor?	Yes		direct from m		eu	item/Lacii.	0.55		2.5	5	0	1
Has FDA granted waiver/exceptio			No	_		ce manufacturer for rep	ackaged product	Box/Carton/I	Bundle/				0	
If yes, attach documentation fro							<u> </u>	Inner Pack:					0	
								Case:	6.89	12	9.25	7.5	0	12
		GT	TIN AND HIBCC PRODUCT I	NFORMATION					0.03	12	5.25	7.0		12
								Pallet:					0	
Saleable Unit of Measure	S	aleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each		1			003	31722018104			COST INFORMATION			WHOLESAL	ER USE ONL	V
Box/Carton/Bundle/Inner Pack X Case		12			202	31722018108			COST INFORMATION			WHOLESAL	EK USE UNL	-1-
X Case		12			203	01722010100		Regular Cos	•		Vendor #:			
T GHOX								Invoice Cost		\$150.00	Whsl. Code	#:		
									-/17/	\$.30.00	Fineline Co			
								As of date:			1			
								Ц						
1			Attach copy of SAFETY Da	ATA SHEET (SDS	S) or non haza	rd letter, PACKAGE INS	ERT, LABEL AND PHOTO OF I	PRODUCT PACK	AGING and BARCODE.					
							ignated 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						
 b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? 	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?	No No	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	No	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?:	Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: No		1-866-827-3647 Yes				
CLASS OF TRADE RESTRICTION:	14	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	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:	No	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 fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:				
F	Name: Phone:	Ships regular ground for 3-10 days receipt:				
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order:		Overnight receipt available:				
Drop Ship service fee billed with each order:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Infor	rmation Required to Process 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?				
Mis	scellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				