

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

Version 2021						Introduction Ty	ype:	Post Launch Change		x F	inal Version			Date:	6/23	3/2024
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214603							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicable:																
DUNS:	11-856-3719									Other Tem	perature Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Gemf	ibrozil Tablets, USP 600 mg							(write	in)					
Selling Unit NDC:	31722-128-60		Unit of Use NDC:		31722-128-60		3317221	128605		Notes						
UDI			CVX Code:			MVX Code:										
Description: Gemfibrozil Tablets, USP 600 mg Is this product to be shipped to customers on ice? No									1							
											d to customers on d			No	1	
Active Ingredient(s): Gemfibrozii, USP																
							b. Contact fo		e excursion qu	estions:						
URL for Additional Product Inform		www.camberpharm	na.com							Name:			Soma Raju			
Address:	800 Centennial A	ve, Suite 1			State:	Address 2:	71	00054		Number:			732-529-042			
City:	Piscataway Customer Service				Email:	-	Zip:		Group E-mail: somaraju@heterousa.com							
Key Contact: Phone Number:	1-866-827-3647	-			Fax:	customerservice@ 732-562-8788	<u>scamber</u>	priarria.com	c Special re	aulatione for	product in any	etatoe?			No	1
Product Therapeutic Classification		Lipid regulating ag	ent		ı ux.	702 002 0700			c. opeciai re	-		s for this product?			No	-
Froduct Therapeutic Classification		Lipid regulating ag	One							Opecial reti	unis requirement	s for this product:			140]
	ADDIT	IONAL PRODUCT IN	JEORMATION			PRODUCT D	DESCRIP	PTION INFORMATION	d Store prod	duct (unit of	sale) upright?				No	1
The same desertion	7,55,111			Direct-Ship O	nly	1 1105001 5			d. otore pro-	•		I-) (l'-l-10				1
The product is? a legend device?		No	Is the Product Is the Product	Unit of Use	niy			60 ct	e. Shelf life:	Protect pro	oduct (unit of sa	ile) from light?			No 24	Mantha
if yes, enter class #		INO	Orphan Drug Status	Offic of Ose		Size:	0	50 Cl	e. Shelf life:	Initial chal	f life at launch (if different).			24	Months Months
a product kit?		No	Orphan Drug Status				6	600 mg		illitiai Silei	i ille at laulicii (ii uiiierent).				WOILLIS
if yes, list NDCs of		INO	FDA Approval Status			Strength:		ooo iiig				ORDER INFORM	IATION			
component parts						B E	. F	Film coated tablet								
reverse numbered?		No				Dosage Form	1:			Unit of Sal	е		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x B	ottle		1 Bottle of 6	0 Tablets		
latex-free?		Yes	Corn Alco	ohol, Animal		Product Shap	ne.	Oval		В	ox/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Oom, Alex	noi, Ailinai		1 Todact Gridp					mpule					
correctional institution block?		No				Product Color	r: V	White to off white			lass		Minimum or	der quantity	?	Yes
opioid?		No					_	Debossed with '1' with two partial			ube					
Cannabinoid?		No	Country of Origin	USA		Product Impri	int: bi	perossed with "1" with two partial			ial Liquid Sgl		W. V 1			
If Unit Dose, is item bar coded to unhospital scanning?	init dose for		Is this product covered u	under the			bi	oisects on other side			ial Liquid Multi ial Powder Sgl		If Yes, how	Each	сп раскаде	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (Yes						ial Powder Multi			Inner/Cartor	/Pack	
ii onii bose, indicate Nbo nere.			Trado rigidomonio rioi (., ., .	103						ther: Write In			Case	or don	
			FOR GENERIC DRUG PR	ODUCTS										1		
					Autl	horized Generic	*If Autho	orized Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB							fields are not applicable	Rec. sell uni	it to custome	r?		Rx billing u	nit to pharm	acv.	
II. Generic Equivalent to What Bra		Lopid										1	TO DINING U	Each	ucy.	
III Conono Equitationi to Tinat En									(Write-in, e.c	g. 1 Vial)		1		Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFOR	MATION									Milliliter		
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes		GLN:	0331722498975					ITEN	I AND PACKING IN	NFORMATION	N		
Is product exempt from DSCSA?			No						 							
If yes, select exemption:					GCP:						Weight Lbs.	Dimensi	ons (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:											rreignt Lus.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			ginal product purcl	hased		Item/Each:		0.17	1.83	1.83	3.4	11.39	1
Is product sold by manufacturer's			Yes	_	direct from mf		-		1							
Has FDA granted waiver/exception		roduct?	No		Provide sourc	e manufacturer for	r repacka	aged product	Box/Carton/l	Bundle/						
If yes, attach documentation from	m FDA.								Case:							
		GT	IN AND HIBCC PRODUCT I	NEORMATION					Case.		4.45	12	8.5	4	408	24
		0.	IN AND THEODY RODGETT	NI OKMATION					Pallet:							
Saleable Unit of Measure	9	Saleable Quantity	HIBCC		GTIN	I-14		Unit of Use GTIN-14	l' dilet.							
X Item/Each	`	1				1722128605		00331722128605								
Box/Carton/Bundle/Inner Pack							1			COSTI	NFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			1033	1722128602	1									
Pallet	_								Regular Cos				Vendor #:			
									Invoice Cost	t (WAC) (\$)		\$10.42	Whsl. Code			
										-	14/0004		Fineline Co	de:		
	-								As of date:	3	/4/2021		Į.			
							1									
 			Attack convet CAFFTY D	TA CLIEFT (OR	C) as see be	diamas DACKACE	INICEDT	LAREL AND BUOTO OF B	DODUCT DACK	ACINO es de	ARCORE					
I		•	Autach copy of SAFETY DA	ATA SHEET (SD	or non hazar			, LABEL AND PHOTO OF P Ited Drop Ship Only.	RODUCT PACK	AGING and E Signature:	SAKCODE.					
*Please provide any additional inf																



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? No	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? No Does the product label bear a CA Prop 65 warning? No	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	Is the product a NIOSH hazardous drug? If yes, indicate which:						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:						
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? No (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); SP#	Comments						
ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments No Phone:						
Is the Product							
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: I-866-827-3647 Is product returnable for credit: Yes						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments) No Comments:	If so, which states? Other requirements? Comments?						
MISCELLANE	DUS 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?