

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

Version 2021						Introduction	Туре:	Post Launch Change	2	Final Version			Date:	6/23/	/2024		
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STOP	RAGE REQUIR	REMENTS*				
Company Name:	Camber Pharmaceuticals,	Inc.				Applica	ation:	ANDA	a. Temperature – Ir	dicate the USP temp	erature range for t	his product.					
Application Number for NDA/ANI	DA/BLA (drug); PMA/510(k	(med device	e):	214	4603					perature Range	Controlled Room		and 25 C (68	° – 77° F)			
Medical Device Class, if applicable:																	
DUNS:	11-856-3719								Othe	r Temperature Range	Requirement						
Proprietary Name (If Applicable) a		Gemfib	rozil Tablets, USP 600 mg							(write in)							
Selling Unit NDC:	31722-128-05		Unit of Use NDC:			UPC:	33172	2128056	Note	5							
UDI			CVX Code:			MVX Code:											
Description:	Gemfibrozil Tablets, USP 6	i00 mg								s product to be shippe				No			
	Camfib								Is thi	s product to be shippe	d to customers on o	dry ice?		No			
Active Ingredient(s): Gemfibrozil, USP b. Contact for temperature excursion questions:																	
URL for Additional Product Inform	ation: www.ca	mberpharma	.com						Nam		6310113.	Soma Raju					
Address:	800 Centennial Ave, Suite	1				Address 2:			Num	ber:		732-529-042	3				
City:	Piscataway					NJ				p E-mail:		somaraju@h	eterousa.con	<u>n</u>			
Key Contact:	Customer Service				Email:		customerservice@camberpharma.com										
Phone Number:					732-562-8788	732-562-8788			c. Special regulations for product in any states?			No					
Product Therapeutic Classification	n: Lipid re	gulating ager	it						Spec	ial returns requiremen	ts for this product?			No			
	ADDITIONAL P					PRODUCT	DESCR	IPTION INFORMATION	d. Store product (u	nit of cale) unright?				No	1		
	ADDITIONAL PI			Direct Of the O	and a	PRODUCT	DESCR	III HON INFORMATION							1		
The product is?	Nie		Is the Product	Direct-Ship C Neither	niiy			500 ct		ect product (unit of s	ale) from light?			No 24	Monthe		
a legend device? if yes, enter class #	No		Is the Product Orphan Drug Status	Refuter		Size:		500 ct	e. Shelf life:	I shelf life at launch (	if different).			24	Months Months		
a product kit?	No		Orphan Drug Status					600 mg	IIIIua	i sheli ile at laulich	in unierenty.				Months		
if yes, list NDCs of			FDA Approval Status			Strength:		g			ORDER INFORM	IATION					
component parts						Dosage For	m-	Film coated tablet									
reverse numbered?	No					Dosage i on				of Sale		What is the		unit?			
co-licensed?	No		Allergens Present						×	Bottle		1 Bottle of 50					
latex-free?	Yes		Corn, Alco	ohol, Animal		Product Sha	ape:	Oval		Box/Carton		(Write-in, e.	g. 1 Box of 10	) Vials)			
preservative-free? correctional institution block?	Yes	_						White to off white		Ampule Glass		Minimum or	dor quantitu	•	Yes		
opioid?	No					Product Col	lor:	white to on white		Tube		Willing	uer quantity	ſ	Tes		
Cannabinoid?	No	_	Country of Origin	USA		Berley		Debossed with '1' with two partial		Vial Liquid Sgl							
If Unit Dose, is item bar coded to u			, ,			Product Imp	print:	bisects on one side and two partial bisects on other side		Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?		
hospital scanning?			Is this product covered u							Vial Powder Sgl			Each				
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	FAA)?	Yes					Vial Powder Multi			Inner/Carton	/Pack			
										Other: Write In			Case				
			FOR GENERIC DRUG PR	ODUCIS					_								
					A	uthorized Generic	*If Aut	thorized Generic, other	PHARMACY ORDER / BILL UNIT								
L Orenne Beek Beting	AB							n fields are not applicable	Rec. sell unit to cu			Rx billing u					
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Lopid						ree. sen unit to cu			KX billing u	Each	icy.						
									(Write-in, e.g. 1 Via	)			Gram				
	DI	RUG SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFOR	MATION								Milliliter				
Does supplier meet DSCSA definit	tion of manufacturer?		Yes	_	GLN:	0331722498975			-	ITEN	I AND PACKING I	NFORMATION					
Is product exempt from DSCSA?			110								<b>D</b> 1	ions (US msm	4- <b>\</b>				
If yes, select exemption: Other exemption - Write in:					GCP:					Weight Lbs.		Width	'	Volume (Cube)	Saleable # Pieces		
Is product repackaged?			No		If ves was o	riginal product pur	rchased		Item/Each:		Depth		Height				
Is product sold by manufacturer's	exclusive distributor?		Yes	_	direct from n		. en acou		1011/20011	1.1	3.5	3.5	6.75	82.69	1		
Has FDA granted waiver/exception	n/exemption for product?		No		Provide sour	rce manufacturer fo	or repac	kaged product	Box/Carton/Bundle	1							
If yes, attach documentation from	n FDA.								Inner Pack:								
		OTIN							Case:	14	14.25	11	7.5	1175.63	12		
		GTIN	I AND HIBCC PRODUCT I	NFORMATION					Pallet:								
Saleable Unit of Measure	Saleable 0	Quantity	HIBCC		GT	IN-14		Unit of Use GTIN-14	ranet.								
X Item/Each	1	,			003	331722128056					1				1		
Box/Carton/Bundle/Inner Pack									C	OST INFORMATION			NHOLESALE	ER USE ONL	Y:		
X Case	12				103	331722128053											
Pallet							_		Regular Cost	(*)		Vendor #:					
	-						-		Invoice Cost (WAC	(\$)	\$59.80	Whsl. Code Fineline Cod					
							-		As of date:	3/8/2021		i menne coo					
												1					
· · · · · · · · · · · · · · · · · · ·	-																
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE	E INSER	RT, LABEL AND PHOTO OF P	RODUCT PACKAGING	and BARCODE.							
*Please provide any additional info	ormation on page 2.					See new p. 3 for	r Design	nated Drop Ship Only.	Sign	ature:							

## HDA🔾

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

Version 2021 For Designated Drop Ship Only Products, Please Use Page 3							
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? 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? 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? No Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number No No No No No No No N	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Is the product a NIOSH hazardous drug?         Is the product a NIOSH hazardous drug?       No         If yes, indicate which:       If yes, indicate which:						
a. On/definition for holder     b. Proper Shipping Name     c. DOT Hazard Class     d. Packing Group     e. Inhalation Hazard?     Is this product regulated for shipment by IATA?     No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:						
(if yes, answer a-e below and provide SDS)       a. UN/Identification Number       b. Proper Shipping Name       c. DOT Hazard Class       d. Packing Group       e. Inhalation Hazard?	REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         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) Special Permit; DOT-SP	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:						
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	No       Registry Program Contact Name:       Comments						
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS         Contact tel. # if product received damaged:       1-866-827-3647         Is product returnable for credit:       Yes						
CLASS OF TRADE RESTRICTION: 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:     No       Restricted to hospital, clinics, and physician offices only:     No       Restricted from US territories? (explain in comments)     No       Comments:     No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						



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

Version 2021 FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	not a designated drop ship, do not complete.
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by:         a. EDI         b. Autofax         c. Fax         d. Phone only         e. Supplier Web Site only         Minimum Order Quantity:         Supplier's Customer Service Number:         Contracted 3PL company / contact #:         Name:         Phone:	Purchase order daily receipt cut off time by supplier         Cut off time:         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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available:       Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?