

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

Version 2021						Introduction Ty	ype:	Post Launch Change		2 Final Version			Date:	7/7/	/2024
			PRODUCT INFORMAT	TION						SPECIAL HA	NDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 204598						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicable:															
DUNS:	11-856-3719									Other Temperature Range	Requirement				
Proprietary Name (If Applicable) as	nd Established Na	me: Feno	fibrate Tablets, USP 145 mg							(write in)	•				
Selling Unit NDC:	31722-596-90		Unit of Use NDC:		31722-596-90		33172259	6909		Notes					
UDI			CVX Code:			MVX Code:									
Description: Fenofibrate Tablets, USP 145 mg Is this product to be shipped to customers on ice? No								1							
		,								Is this product to be shipp				No	-
Active Ingredient(s):		Fenofibrate, USP										•			_
								b. Contact for	temperature excursion of	uestions:					
URL for Additional Product Inform		www.camberpharm	na.com							Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:				Number:		732-529-042			
City:	Piscataway				State:	NJ Zip : 08854				Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service	_				customerservice@camberpharma.com 732-562-8788								7	
Phone Number:	1-866-827-3647	n : "			Fax:	732-562-8788			c. Special reg	ulations for product in an	-			No	-
Product Therapeutic Classification	1:	Peroxisome prolife	rator receptor alpha (PPARα)	activator						Special returns requireme	nts for this product?			No	
										-					
	ADDITI	ONAL PRODUCT IN	IFORMATION			PRODUCT DI	ESCRIPT	ION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	only					Protect product (unit of	sale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	90	ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.				Initial shelf life at launch	(if different):				Months
a product kit?		No				Strength:	14	5 mg							
if yes, list NDCs of			FDA Approval Status								ORDER INFOR	MATION			
component parts		ls.				Dosage Form:	ı: Fili	m coated tablet		Helt of Oole		\M/ls a4 ia 4ls a	NDC aalliaa		
reverse numbered?		No	Allermana Dracent							Unit of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Ov	al, biconvex		x Bottle Box/Carton		1 Bottle of 9	g. 1 Box of 1	O \/iolo\	
preservative-free?		Yes	Dairy, Lactose, S	oy, Alcohol, Sι	ıgar	Product Shap	oe:	ai, diconvex		Ampule		(vviite-iii, e.	y. 1 bux 01 11	U Viais)	
correctional institution block?		No					VA/F	nite to off white		Glass		Minimum or	der auantity	12	Yes
opioid?		No				Product Color	r: "	inc to on write		Tube		Million O	uci quantity	•	103
Cannabinoid?		No	Country of Origin	India			. Del	bossed with 'J' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		, ,			Product Impri	int:	d '136' on the other side		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No					Vial Powder Mul	ti		Inner/Carton	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS											
					Auth			ized Generic, other		F	PHARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fie	elds are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharma	асу:	
II. Generic Equivalent to What Bran	nd?:	Tricor											Each	-	
		-							(Write-in, e.g.	1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION								Milliliter		
				_											
Does supplier meet DSCSA definit	ion of manufactur	er?	Yes	_	GLN:	0331722498975				ITE	M AND PACKING I	NFORMATION	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msm	•	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		ginal product purch	hased		Item/Each:	0.22	2.11	2.11	3.85	17.14	1
Is product sold by manufacturer's			Yes	4	direct from mf										
Has FDA granted waiver/exception		oduct?	No		Provide source	e manufacturer for	repackag	ged product	Box/Carton/B	undle/					
If yes, attach documentation fron	n FDA.								Inner Pack:						
		CT	IN AND HIBCC PRODUCT IN	IEODMATION					Case:	6.4	13.65	9.5	5.25	680.79	24
		GI	IN AND HIBCC PRODUCT II	NFORWATION					Pallet:						
Saleable Unit of Measure	9	Saleable Quantity	HIBCC		GTIN	-14	1	Init of Use GTIN-14	railet.						
X Item/Each		1	TIBEE			1722596909		0331722596909							
Box/Carton/Bundle/Inner Pack										COST INFORMATION	l		WHOLESALI	ER USE ON	LY:
X Case		24			2033	1722596903									
Pallet									Regular Cost			Vendor #:			
									Invoice Cost	(WAC) (\$)	\$25.00	Whsl. Code	#:		
]											Fineline Co	de:		
									As of date:	7/26/2022					
]														
1									ļ			<u> </u>			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non hazard				RODUCT PACK						
	ormation on page	2				See new p. 3 for D	Docionato	d Dron Shin Only		Signature:					



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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?