

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

Version 2021						Introduction Ty	/pe: New Item		x Final Version	1		Date:	6/23/	/2024
			PRODUCT INFORMA	TION					SPECIAL	HANDLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Applicati	on: ANDA	a. Temperatu	re - Indicate the USP t	emperature range for	this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 205977				5977		-	- La romporato	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
Medical Device Class, if applicab			•						,					
DUNS:	11-856-3719								Other Temperature Ra	inge Requirement				
Proprietary Name (If Applicable) a	nd Established Na	me: Pitava:	statin Tablets 2 mg						(write in)	- '				
Selling Unit NDC:	31722-876-90		Unit of Use NDC:		31722-876-90		331722876902		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Pitavastatin Table	ets 2 mg							Is this product to be sh	nipped to customers on	ice?		No	1
•		· ·								nipped to customers on			No	1
Active Ingredient(s):		Pitavastatin calcium												
							b. Contact fo	r temperature excursio	n questions:					
URL for Additional Product Inform		www.camberpharma	a.com						Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway					Zip: 08854		Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service 1-866-827-3647					camberpharma.com	c. Special regulations for product in any states?			NI.	1			
Phone Number:		11110 0 1 1 1 1 1 1 1	- 1-1-1-1-1 (-1-11-)		Fax:	732-562-8788		c. Special re		-			No	-
Product Therapeutic Classification	n:	HMG-CoA reductas	e inhibitor (statin)						Special returns require	ements for this product?	,		No	_
	ADDITI	ONAL PRODUCT IN	CODMATION			BRODUOT B	ESSENTION INFORMATION	_						7
	ADDITI	ONAL PRODUCT IN				PRODUCT D	ESCRIPTION INFORMATION	d. Store prod	luct (unit of sale) uprigi				No	_
The product is?			Is the Product	Direct-Ship (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 #		1	Orphan Drug Status					_	Initial shelf life at lau	nch (if different):				Months
a product kit?		No	FD.4. 4			Strength:	2 mg			ORDER INFOR	MATION			
if yes, list NDCs of			FDA Approval Status				Film coated tablet			ORDER INFOR	MATION			
component parts reverse numbered?		No				Dosage Form	: Filli Coated tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					_	x Bottle		1 Bottle of 9			
latex-free?		Yes					Round, bevel edged,		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Dairy, Lac	tose, Casein		Product Shap	e: biconvex		Ampule		, , , ,		,	
correctional institution block?		No				Product Color	White to off-white		Glass		Minimum o	der quantity	?	Yes
opioid?		No				Product Color	r :		Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri	Debossed with 'H2' on one		Vial Liquid S	gl				
If Unit Dose, is item bar coded to u	nit dose for					r roduct impri	side and 'P' on other side		Vial Liquid M				ch package	type?
hospital scanning?			Is this product covered u						Vial Powder		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (ГАА)?	No				Vial Powder			Inner/Carton	/Pack	
									Other: Write	In		Case		
			FOR GENERIC DRUG PR	ODUCTS										
							*If A all a size of O a series of the se			PHARMACY ORDE	D / DILL LINIT			
				_	Aut	horized Generic	*If Authorized Generic, other section fields are not applicable			PHARMACT URDE				
	AB						section fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharma	асу:	
II. Generic Equivalent to What Brai	nd?:	Livalo						00/-11- 1	4 1 1 2 - 1)			Each		
		DRIIG SUBBI	Y CHAIN SECURITY ACT (DSCSA) INFO	2MATION .			(Write-in, e.g	. 1 Viai)			Gram Milliliter		
		DRUG SULLE	T CHAIN SECONTT ACT	DSCSA) INI CI	MATION							Millille		
Does supplier meet DSCSA definit	tion of manufactur	er?	Yes	7	GLN:	0331722498975				ITEM AND PACKING	INFORMATIO	١		
Is product exempt from DSCSA?	or manaraota.		No		02	0001122100010						•		
If ves. select exemption:					GCP:					Dimens	sions (US msn	ite \	Volume	Saleable #
other exemption - Write in:					GUF.				Weight Li	os. Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If ves was ori	ginal product purcl	hased	Item/Each:						
			Yes		direct from mf				0.10	1.55	1.55	3.08	7.40	1
	exclusive distribu	itor?	res				repackaged product	Box/Carton/E						
Has FDA granted waiver/exception	exclusive distribun/exemption for pr		No	7	FIOVIUE SOUIC	e manuracturer for			Sundle/					
	n/exemption for pr				Frovide Sourc	e manuracturer for	gp	Inner Pack:	Bundle/					24
Has FDA granted waiver/exception	n/exemption for pr	oduct?	No		Frovide sourc	e manuracturer for	- Spanings of Product			9.75	7	4 15	283 24	2-7
Has FDA granted waiver/exception	n/exemption for pr	oduct?		NFORMATION	Frovide Source	e manuracturer for	- Francisco Producti	Inner Pack:	2.65	9.75	7	4.15	283.24	
Has FDA granted waiver/exception If yes, attach documentation from	n/exemption for pr n FDA.	oduct?	No N AND HIBCC PRODUCT II	NFORMATION				Inner Pack:		9.75	7	4.15	283.24	
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pr n FDA.	GTII	No	NFORMATION	GTIN	I-14	Unit of Use GTIN-14	Inner Pack: Case:		9.75	7	4.15	283.24	
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each	n/exemption for pr n FDA.	oduct?	No N AND HIBCC PRODUCT II	NFORMATION	GTIN			Inner Pack: Case:	2.65					V
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	n/exemption for pr n FDA.	GTII	No N AND HIBCC PRODUCT II	NFORMATION	GTIN 0033	I-14 1722876902	Unit of Use GTIN-14	Inner Pack: Case:					283.24 ER USE ONL	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTII	No N AND HIBCC PRODUCT II	NFORMATION	GTIN 0033	I-14	Unit of Use GTIN-14	Inner Pack: Case: Pallet:	2.65 COST INFORMAT					Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	n/exemption for pr n FDA.	GTII	No N AND HIBCC PRODUCT II	NFORMATION	GTIN 0033	I-14 1722876902	Unit of Use GTIN-14	Inner Pack: Case: Pallet: Regular Cos	2.65 COST INFORMAT	ION	Vendor #:	WHOLESAL		Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTII	No N AND HIBCC PRODUCT II	NFORMATION	GTIN 0033	I-14 1722876902	Unit of Use GTIN-14	Inner Pack: Case: Pallet:	2.65 COST INFORMAT	ION	Vendor #:) Whsl. Code	WHOLESALI		.Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTII	No N AND HIBCC PRODUCT II	NFORMATION	GTIN 0033	I-14 1722876902	Unit of Use GTIN-14	Inner Pack: Case: Pallet: Regular Cost Invoice Cost	2.65 COST INFORMAT	ION	Vendor #:	WHOLESALI		Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTII	No N AND HIBCC PRODUCT II	NFORMATION	GTIN 0033	I-14 1722876902	Unit of Use GTIN-14	Inner Pack: Case: Pallet: Regular Cos	COST INFORMAT (WAC) (\$)	ION	Vendor #:) Whsl. Code	WHOLESALI		Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTII	No N AND HIBCC PRODUCT II	NFORMATION	GTIN 0033	I-14 1722876902	Unit of Use GTIN-14	Inner Pack: Case: Pallet: Regular Cost Invoice Cost	COST INFORMAT (WAC) (\$)	ION	Vendor #:) Whsl. Code	WHOLESALI		Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTII	NO N AND HIBCC PRODUCT II HIBCC		GTIN 0033 2033	I-14 1722876902 1722876906	Unit of Use GTIN-14	Inner Pack: Case: Pallet: Regular Cos Invoice Cost As of date:	2.65 COST INFORMAT (WAC) (\$) 4/30/2024	ION	Vendor #:) Whsl. Code	WHOLESALI		.Y:



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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? 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?