

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

Version 2021						Introduction Type:	New Item		Final Version			Date:	8/5/	5/2021
			PRODUCT INFORMA	TION					SPECIAL HAI	IDLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals 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): 203825 Temperature Range Controlled Room - between 20 and 25 C (68° – 77° F)														
Medical Device Class, if applica														
DUNS:	826774775							1	Other Temperature Range	Requirement				
Proprietary Name (If Applicable)	and Established Na	ame: Nebiv	olol Tablet 10mg 30ct					Ī	(write in)					
Selling Unit NDC:	31722-587-30		Unit of Use NDC:			UPC: 3317	22587303	İ	Notes					
UDI			CVX Code:			MVX Code:		Ĭ						
Description:	Oral Solid Tablet	White to Off White	 Triangle-shaped, Upper: 'J' L	ower: '10'				ī	Is this product to be shippe	d to customers on	ice?		No	1
2 coonplicin	Oral Colla Tablot,	, TTIMO IO OII TTIMO,	mangio onapoa, oppon o z	.0					Is this product to be shippe				No	-
Active Ingredient(s):		Nebivolol						†			,			7
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inforr	nation:	www.camberph	arma.com					Ĭ	Name:		Soma Raju			
Address:	800 Centennial A	ve				Address 2:			Number:		732-529-042			
City:	Pisacataway				State:	NJ	08854		Group E-mail:		somaraju(<u> Pheterous</u>	a.com	
Key Contact:	Customer Service	9			Email:	customerservice@c	amberpharma.com_							-
Phone Number:	732-529-0430	I			Fax:	732-562-8788		c. Special reg	gulations for product in any					4
Product Therapeutic Classification	on:	Beta Blockers							Special returns requirement	ts for this product?				
	4.5.5151		TABLE LEIAN											7
	ADDITI	IONAL PRODUCT IN	FORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Only	У				Protect product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	30CT	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						Initial shelf life at launch	(if different):			24	Months
a product kit?		No				Strength:	10MG			ODDED INCOD	MATION			
if yes, list NDCs of			FDA Approval Status			_	OI O-E-I T-I-I-I			ORDER INFOR	MATION			
component parts reverse numbered?		No				Dosage Form:	Oral Solid - Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 3		uiiit:	
latex-free?		Yes	Allergens Fresch				Triangle-shaped		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:	· · · · · · · · · · · · · · · · · · ·		Ampule		(3	,	
correctional institution block?		Yes				Product Color:	White to Off White		Glass		Minimum o	rder quantity	<i>i</i> ?	Yes
opioid?		Yes				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Upper: 'J' Lower: '10'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					r roduct imprint.			Vial Liquid Multi				ich package	type?
hospital scanning?		No	Is this product covered u						Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?					Vial Power Multi			Inner/Cartor	n/Pack	
								<u>l </u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
						sharinad Canasia *If A	sheetined Conceils ashee		В	HARMACY ORDER	2 / DILL LINIT			
					Au		uthorized Generic, other on fields are not applicable			TARMACT ORDER				
I. Orange Book Rating:	AB	D				3600	on neids are not applicable	Rec. sell unit	to customer?	-	Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bra	and?:	Bystolic						OM-trailed to	4 1 1 2 - 1)			Each		
		DRIIG SIIDDI	LY CHAIN SECURITY ACT	(DSCSA) INFORM	ATION			(Write-in, e.g	. 1 Viai)			Gram Milliliter		
		DRUG SUFFI	ET CHAIN SECONTT ACT	(DSCSA) IN ORM	ATION							wiiiiiitei		
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes	G	LN:	0331722000000			ITE	M AND PACKING I	INFORMATIO	N		
Is product exempt from DSCSA?			No			000112200000								
If ves. select exemption:					CP:			i		Dimens	ions (US msn	nte \	Volume	Saleable #
Other exemption - Write in:					icr.			1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	lf.	ves was or	iginal product purchase	d	Item/Each:		Берш			(Gubc)	
Is product sold by manufacturer's	s exclusive distribu	utor?	No		irect from m			inomy Euroni	0.05		3	1.6		1
Has FDA granted waiver/exception			No	_		e manufacturer for repa	ckaged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro						·		Inner Pack:						
								Case:	1.95	10	6.8	4.6	0.14	24
		GTI	IN AND HIBCC PRODUCT I	NFORMATION					1.55	10	0.0	4.0	0.14	24
								Pallet:						
Saleable Unit of Measure	8	Saleable Quantity	HIBCC		GTI		Unit of Use GTIN-14							
X Item/Each		1			0033	31722587303			COST INFORMATION			WILLOLE CH	ER USE ONL	I V.
Box/Carton/Bundle/Inner Pack					2000	1700507007			COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case		24			2033	31722587307		Regular Cost			Vendor #:			
r allet								Invoice Cost		\$20.00	Vendor #: Whsl. Code	#-		
								IIIVOICE COST	(1170) (4)	φ36.20	Fineline Co			
								As of date:						
	_		-					11			1			
			Attach copy of SAFETY D	ATA SHEET (SDS)	or non hazaı	d letter, PACKAGE INSE	RT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE.		1			



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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?	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? 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)		REMS o	r REGISTRY RESTRICTIONS			
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group		Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No			
e. Inhalation Hazard?	No					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No				
Passenger & Cargo		Transfer of the state of the st				
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		Comments				
Special Provision (listed in Column 7 of 49 CFR 172.101);						
SP#		Registry:	No	Dhara		
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:		
Is the Product						
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?:	No No	Contact tel. # if product received damaged: Is product returnable for credit:	732-529-0430 Yes			
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	contact email: custor	nerservice@camberpharma.com			
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No No	product in certain states? If so, which states? Other requirements? Comments?				
Comments:						
MI	SCELLANEC	US 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 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	Fax Number: Fax Number: Phone No.:	Shipping lead time of PO: Hours Days				
, ,	Site Address:	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:				
Expedited Freight Charge	es 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 phane Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in commonments:	ffices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Inform	mation 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	cellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				