

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

Version 2021						Introduction Type	e: New Item		Final Version			Date:	8/5/	/2021
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUIR	REMENTS*		
Company Name:	Camber Pharmac	euticals				Application	: ANDA	a. Temperatu	re - Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203825					<u> </u>	- an i omporato	Temperature Range	Controlled Room		and 25 C (68	° – 77° F)			
Medical Device Class, if applicable:														
DUNS:	826774775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	me: Nebivo	olol Tablet 20mg 30ct					T	(write in)	·				
Selling Unit NDC:	31722-588-30		Unit of Use NDC:				1722588300		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Description: Oral Solid Tablet, White to Off White, Triangle-shaped, Upper: 'J' Lower: '11' Is this product to be shipped to customers on ice? No									1				
		,							Is this product to be shippe				No	1
Active Ingredient(s):		Nebivolol						1			•			_
						b. Contact for	b. Contact for temperature excursion questions:							
URL for Additional Product Inform		www.camberpha	arma.com						Name:		Soma Raju			
Address:	800 Centennial Av	ve				Address 2:			Number:		732-529-0423			
City:	Pisacataway				State:	NJ	08854	_	Group E-mail:		somaraju@	heterousa	.com	
Key Contact:	Customer Service	1			Email:		©camberpharma.com							
Phone Number:	732-529-0430	la . a			Fax:	732-562-8788		c. Special reg	ulations for product in any					-
Product Therapeutic Classification	1:	Beta Blockers							Special returns requirement	is for this product?				
	ADDITIO	ONAL PROPUST IN	FORMATION.			BRODUST DE	ACRIPTION INFORMATION	<b>-</b> l.a						7
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship C	nly				Protect product (unit of sa	ile) 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:	20MG			ORDER INFORM	AATION			
if yes, list NDCs of			FDA Approval Status			_	O10-Ed T-blad			ORDER INFORM	IATION			
component parts reverse numbered?		Ne				Dosage Form:	Oral Solid - Tablet		Unit of Sale		What is the I	NDC calling	unit?	
co-licensed?		No No	Allergens Present						x Bottle		1 bottle of 30		uiiit:	
latex-free?		Yes	Anergens i resent				Triangle-shaped		Box/Carton		(Write-in, e.c		) Vials)	
preservative-free?		Yes				Product Shape:	g.u 2ap 2.2		Ampule		(	,		
correctional institution block?		Yes					White to Off White		Glass		Minimum or	der quantity	?	Yes
opioid?		Yes				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	Upper: 'J' Lower: '11'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					Froduct imprint	•		Vial Liquid Multi		If Yes, how r		ch package	type?
hospital scanning?		No	Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	TAA)?					Vial Power Multi			Inner/Carton	/Pack	
								<u> </u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Au		Authorized Generic, other			IARMACY ORDER	/ BILL UNIT			
	AB					SE	ction fields are not applicable	Rec. sell unit	to customer?	-	Rx billing un		acy:	
II. Generic Equivalent to What Bran	nd?:	Bystolic										Each		
		DDIIO GUDDI	Y CHAIN SECURITY ACT (	DOOD AV INFOR	MATION			(Write-in, e.g.	1 Vial)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION							Milliliter		
Does supplier meet DSCSA definit	ion of manufactur	or?	Yes	_	GLN:	0331722000000			ITEN	I AND PACKING I	NEORMATION			
Is product exempt from DSCSA?	ion of manufactur	ei :	No	-	GLIV.	0331722000000				I AND I AGIGNO	W OKIMATION			
•			- 110					-		Dimensi	(116	4-1		
If yes, select exemption: Other exemption - Write in:					GCP:				Weight Lbs.	Dimens Depth	ons (US msm Width	•	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If was was ar	iginal product purcha	and	Item/Each:		Depth		Height	(Cube)	
Is product repackaged:	avelusiva distribu	ıtor?	No	-	direct from m		seu	item/Each.	0.05		1.6	3		1
Has FDA granted waiver/exception			No	-		e manufacturer for re	epackaged product	Box/Carton/B	undle/					
If yes, attach documentation from							, parting on product	Inner Pack:						
								Case:	1.95	10.2	4.4	7	0.14	24
		GTI	N AND HIBCC PRODUCT I	NFORMATION					1.95	10.2	4.4	′	0.14	24
								Pallet:						
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTII		Unit of Use GTIN-14							
X Item/Each		1			003	31722588300			0007 11150011 151511					
Box/Carton/Bundle/Inner Pack		24				170050006			COST INFORMATION		, v	WHOLESAL	ER USE ONL	LY:
X Case		24			2033	31722588304					Vendor #:			
Pallet	1							Regular Cost Invoice Cost	(WAC) (\$)	#20.00	Whsl. Code	#-		
								IIIVOICE COST	(1170) (4)	\$36.20	Fineline Code			
								As of date:						
											1			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE IN	SERT, LABEL AND PHOTO OF	PRODUCT PACKA	GING and BARCODE.					
	rmation on page	2	÷ ÷		-		signated Drop Ship Only.		Signature:					



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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				
<ul> <li>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?</li> <li>Is the product a CA Prop 65 carcinogen?</li> <li>Is the product a CA Prop 65 reproductive toxicant?</li> <li>Does the product label bear a CA Prop 65 warning?</li> </ul>	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: customerservice@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:				



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

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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?				