

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

Version 2021						Introduction Type	e: New Item			x Final Version			Date:	6/1/2	2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	IDA/BLA (drug); PN	/IA/510(k)(med devi	ce):	203825			1			Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applical															
DUNS:	11-856-3719									Other Temperature Range I	Requirement	Excursions p	permitted to 1	5-30°C (59-8	86°F)
Proprietary Name (If Applicable) a	and Established Na	me: Nebiv	rolol Tablets 20 mg							(write in)					
Selling Unit NDC:	31722-588-30		Unit of Use NDC:	3172	2-588-30		31722588300			Notes					
UDI			CVX Code:			MVX Code:									
Description:	Nebivolol Tablets	20 mg								Is this product to be shipped	to customers on	ce?		No	
-										Is this product to be shipped				No	
Active Ingredient(s):		Nebivolol hydrochle	oride												
									b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inforn		www.camberpharm	na.com							Name:		Soma Raju			
Address:	800 Centennial Av	/e, Suite 1				Address 2: NJ	08854			Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service					customerservice@ca				Group E-mail:		somaraju@r	neterousa.com	<u>11</u>	
Phone Number:	1-866-827-3647	·				732-562-8788	апьстрпанна.сон		c. Special regi	ulations for product in any	states?			No	1
Product Therapeutic Classificatio		Beta-adrenergic blo	ocking agent							Special returns requirement				No	
l rouge morapouno oracomouno										oposiai rotarrio roquiromoni	o for ano product.			110	
	ADDITIO	ONAL PRODUCT IN	NFORMATION			PRODUCT DES	SCRIPTION INFORMATIO	N	d. Store produ	ct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship Only						Protect product (unit of sa	lo) from light?			No	1
a legend device?		No	Is the Product	Unit of Use			30 ct		e. Shelf life:	Protect product (unit of Sa	ile) iroin light?			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	50 01			Initial shelf life at launch (	if different):			2.7	Months
a product kit?		No				a	20 mg								
if yes, list NDCs of			FDA Approval Status			Strength:	-				ORDER INFORI	MATION			
component parts						Dosage Form:	Tablet								
reverse numbered?		No				200490101111				Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 3			
latex-free?		Yes				Product Shape:	Triangular, biconvex			Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes					White to off-white			Ampule Glass		Minimum o	dor augntity		Yes
opioid?		No				Product Color:	writte to oir-writte			Tube		William O	uer quaritity	•	Tes
Cannabinoid?		No	Country of Origin	India			Debossed with 'J' on on	e side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for	110	,g			Product Imprint	and '11' on the other sid	le		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	inder the						Vial Powder Sgl			Each		••
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ΓAA)? No						Vial Powder Multi			Inner/Cartor	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
					Autho		Authorized Generic, other				ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					SE	ection fields are not applica	able	Rec. sell unit t	to customer?	_	Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	and?:	Bystolic											Each		
		DDIIO OUDD	LV OHAIN OF OUR TV ACT	DOOD AV INFORMATI	ION .				(Write-in, e.g.	1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	DSCSA) INFORMATI	ON								Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	or?	Yes	GLN:		0331722498975				ITEN	I AND PACKING I	NEORMATIO	V		
Is product exempt from DSCSA?	or manaractur		No	- GEN.	.	000.722-00070							<del></del>		
If ves. select exemption:				GCP:							Dimene	ions (US msn	nts )	Volume	Saleable #
Other exemption - Write in:				GCP	. [					Weight Lbs.	Dimens	Width	Height	(Cube)	Saleable #
Is product repackaged?			No	If ves	s was origi	inal product purcha	sed		Item/Each:		1			I .	
Is product sold by manufacturer's	s exclusive distribu	itor?	Yes		t from mfr					0.06	1.52	1.52	2.54	5.87	1
Has FDA granted waiver/exceptio	n/exemption for pr	oduct?	No	Provi	ide source	manufacturer for re	epackaged product		Box/Carton/Bu	ındle/					
If yes, attach documentation from	m FDA.								Inner Pack:						
									Case:	1.95	10	6.75	4.25	286.88	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION											
Saleable Unit of Measure									Pallet:						
X Item/Each	S	aleable Quantity	HIBCC		GTIN-	722588300	Unit of Use GTIN-1- 00331722588300	4							
X Item/Each Box/Carton/Bundle/Inner Pack		-			00331	12200000	00331722300300			COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			20331	722588304				OCCI INI CRIMATION			WIOLLOAL	EIN OOL ONE	
Pallet								- []	Regular Cost			Vendor #:			
									Invoice Cost (	WAC) (\$)	\$7.00	Whsl. Code	#:		
												Fineline Co			
									As of date:	4/15/2024					
								- []							
1.1								1							
<del> </del>				T. OUEET ::			0=DT   4DE: :::			0.000 1.000		ļ			
*Please provide any additional inf			Attach copy of SAFETY DA	ATA SHEET (SDS) or r			SERT, LABEL AND PHOT			GING and BARCODE. Signature:					



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#### Version 2021

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?	SDS Hazard Classification							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive							
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No							
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:							
(If yes, attach SDS with special instructions.)	NFPA Storage Level:							
e. Does the product contain DEHP?								
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug? No							
(if yes, answer a-e below and provide SDS)	If yes, indicate which:							
a. UN/Identification Number								
b. Proper Shipping Name								
c. DOT Hazard Class	Hazardous Waste Identification							
d. Packing Group								
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics							
Is this product regulated for shipment by IATA?								
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS							
a. UN/Identification Number								
b. Proper Shipping Name	Is there a REMS on this product?							
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?							
d. Packing Group	Website URL:							
e. Inhalation Hazard?								
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No							
Passenger	Limited Distribution Requirement							
Cargo	Comments / Details: (For example, iPledge program?)							
Passenger & Cargo								
Is this a reportable quantity? No	REMS: No							
RQ Threshold:	REMS Program Manager Name: Phone:							
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:							
Is this product shipped utilizing an authorized DOT exception or Special Permit?  No (if yes, identify method below)	Wholesale distributor support:							
No (if yes, identify method below)  Limited Quantity	Provider Name:  Site Enrollment Number assigned  DEA #:  NCPDP#:							
Consumer Commodity, ORM-D	by Supplier: NPI #:							
Small Quantity (49 CFR 173.4)	Бу Сарриет.							
Special Permit; DOT-SP	Comments							
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#	Registry: No							
	Registry Program Contact Name: Phone:							
ADD'L STORAGE INFORMATION	Comments							
Is the Product								
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS							
Controlled by State(s)? No Listed Chemical (List I or II) No								
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 732-529-0430							
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:							
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:	Special regulations or returns requirements for this							
Restricted to hospital, clinics, and physician offices only:  No	product in certain states?							
Restricted from US territories? (explain in comments)  No	If so, which states? Other requirements? Comments?							
Comments:								
- Commonted								
_ MICCELL AND	US NOTES and/or Image of Product Barcode:							
MISCELLANEO	03 NOTES and/or image of Product Barcoue.							



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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?