

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

						Introduction Type:	New Item		Final Version			Date:	8/5/	2021
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	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 applicable:														
DUNS:	826774775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable)	and Established Na	ame: Nebivo	olol Tablet 5mg 90ct					T	(write in)					
Selling Unit NDC:	31722-586-90		Unit of Use NDC:			UPC: 3317	22586900	1	Notes					
UDI			CVX Code:			MVX Code:		1						
Description: Oral Solid Tablet, Light Orange, Triangle-shaped, 'Upper: 'J' Lower: '9'							7	Is this product to be shippe	d to customers on in	e?		No	1	
2 coonplication	Oran Cona Tablot,	Light Orango, mang.	io chapoa, oppon o zono	. •					Is this product to be shippe				No	1
Active Ingredient(s):		Nebivolol						†			.,			
						b. Contact for temperature excursion questions:								
URL for Additional Product Inforr	mation:	www.camberpha	arma.com					1	Name:		Soma Raju			
Address:	800 Centennial A	ve				Address 2:			Number:		732-529-042			
City:	Pisacataway				State:	NJ	08854		Group E-mail:		somaraju@	heterousa	i.com	
Key Contact:	Customer Service	1			Email:	customerservice@c	amberpharma.com_							
Phone Number:	732-529-0430				Fax:	732-562-8788		c. Special reg	gulations for product in any					
Product Therapeutic Classification	on:	Beta Blockers							Special returns requiremen	ts for this product?				
								_						-
	ADDITI	ONAL PRODUCT INF	FORMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Onl	ly				Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	90CT	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.			Initial shelf life at launch	if different):			24	Months
a product kit?		No				Strength:	5MG							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts		ls.				Dosage Form:	Oral Solid - Tablet		Unit of Sale		What is the	NDC aalliaa		
reverse numbered? co-licensed?		No No	Allergens Present						x Bottle		1 bottle of 90		unitr	
latex-free?		Yes	Allergens Fresent				Triangle-shaped		Box/Carton		(Write-in, e.g		n Viale)	
preservative-free?		Yes				Product Shape:	mangic snaped		Ampule		(**************************************	g. 1 DOX 01 1	o viais)	
correctional institution block?		Yes					Light Orange		Glass		Minimum or	der quantity	?	Yes
opioid?		Yes				Product Color:			Tube				-	
Cannabinoid?		No	Country of Origin	India		Boo dood looseled	Upper: 'J' Lower: '9'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					Product Imprint:			Vial Liquid Multi		If Yes, how i	many of whi	ch 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/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
				_										
				L	Aut		thorized Generic, other			IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					section	on fields are not applicable	Rec. sell unit					асу:	
								_	to customer?	_	Rx billing ur	nt to pharma		
II. Generic Equivalent to What Bra		Bystolic									Rx billing ur	Each		
II. Generic Equivalent to What Bra								(Write-in, e.g.			Rx billing ur	Each Gram		
II. Generic Equivalent to What Bra			LY CHAIN SECURITY ACT (	(DSCSA) INFORM	MATION			(Write-in, e.g.			Rx billing ur	Each		
	and?:	DRUG SUPPL						(Write-in, e.g.	. 1 Vial)	AND DACKING IN		Each Gram Milliliter		
Does supplier meet DSCSA defin	and?:	DRUG SUPPL	Yes		MATION GLN:	0331722000000		(Write-in, e.g.	. 1 Vial)	I AND PACKING IN		Each Gram Milliliter		
Does supplier meet DSCSA defin Is product exempt from DSCSA?	and?:	DRUG SUPPL			GLN:			(Write-in, e.g.	. 1 Vial)		IFORMATION	Each Gram Milliliter		
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption:	and?:	DRUG SUPPL	Yes					(Write-in, e.g.	. 1 Vial)	Dimensi	IFORMATION	Each Gram Milliliter	Volume	Saleable #
Does supplier meet DSCSA defin is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	DRUG SUPPL	Yes No		GLN: GCP:	0331722000000			. 1 Vial) ITEI Weight Lbs.		IFORMATION ons (US msm Width	Each Gram Milliliter	Volume (Cube)	Saleable #
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?:	DRUG SUPPL	Yes No	G G	GLN: GCP: f yes, was or	0331722000000	1	(Write-in, e.g.	. 1 Vial)	Dimensi	IFORMATION	Each Gram Milliliter		
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	and?: iition of manufactur s exclusive distribu	DRUG SUPPL	Yes No No	C	GLN: GCP: f yes, was or direct from m	0331722000000 lginal product purchased		Item/Each:	Weight Lbs.	Dimensi	IFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height		Pieces
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Does supplier meet DSCSA defin Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptic If yes, attach documentation fro	and?:  ition of manufactur  s exclusive distribution for prom FDA.	DRUG SUPPL rer?  utor? roduct?  GTII Saleable Quantity	Yes No No No No No No	C C	GLN: GCP: f yes, was or direct from m Provide source GTII 0033	0331722000000  Iginal product purchaser fr? se manufacturer for repa	ckaged product	Item/Each: Box/Carton/B Inner Pack: Case:	Weight Lbs.  0.1  Bundle/	Dimensi Depth	ons (US msm Width 2	Each Gram Milliliter ts.) Height 4	(Cube)	Pieces 1 24
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

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	SI	S 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 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	No	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?	No				
Comments:							
MI	SCELLANEC	US NOTES and/or Image of Product Barcode:					



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

#### Version 2021

#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated D	Orop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
	x Number:	
	x Number:	Shipping lead time of PO: Hours Days
	one No.:	China cama day far nayt day receipts
e. Supplier Web Site only Site Minimum Order Quantity:	e Address:	Ships same day for next day receipt: Ships for second day receipt:
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:		Ships regular ground for 5-10 days receipt.
Phone:		
Expedited Freight Charges or Other De	esignated 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:		Days of week overnight is available: Monday
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Class of Trade Restr	riction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals	c clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	s, clinics and physician onices	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:		Phone: Phone #:
Restricted from US territories? (explain in comments)		Order receipt method: Fax: Fax #:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Information Require	ed to Process PO:	Return Instructions
Patient Procedure Date:		Contact # if product is received damaged:
Physician Name:		Is product returnable for credit:
Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
Miscellaneous No	otes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?