

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

Version 2021						Introduction Type	: New Item		Final Version			Date:	8/5/	2021
			PRODUCT INFORMA	TION					SPECIAL HANI	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	Camber Pharmac	euticals				Application:	ANDA	a. Temperature	- Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203825								Controlled Room -		nd 25 C (68	° – 77° F)			
Medical Device Class, if applicable:														
DUNS:	826774775							* c	Other Temperature Range R	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	me: Nebivo	lol Tablet 2.5mg 30ct					Ţ	(write in)					
Selling Unit NDC:	31722-585-30		Unit of Use NDC:			UPC: 331	1722585309	1	lotes					
UDI			CVX Code:			MVX Code:		I						
Description:	Oral Solid Tablet.	White to Off White. T	riangle-shaped, Upper: 'J' L	ower: '8'				ī l	s this product to be shipped	to customers on ic	e?		No	
	, , , , , , , , , , , , , , , , , , , ,	,	9,						s this product to be shipped				No	
Active Ingredient(s):		Nebivolol						†			•			
							b. Contact for to	emperature excursion que	estions:					
URL for Additional Product Inform		www.camberpha	arma.com						lame:		Soma Raju			
Address:	800 Centennial Av	/e				Address 2:			lumber:		732-529-042			
City:	Pisacataway				State:	NJ	08854		Froup E-mail:		somaraju@	heterousa	<u>.com</u>	
Key Contact:	Customer Service	!			Email:		camberpharma.com							
Phone Number:	732-529-0430	D . D			Fax:	732-562-8788			ations for product in any					
Product Therapeutic Classification	n:	Beta Blockers						8	Special returns requirements	s for this product?				
														1
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sal	le) 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						nitial shelf life at launch (i	f different):			24	Months
a product kit?		No				Strength:	2.5MG			ODDED INCODE	ATION			
if yes, list NDCs of			FDA Approval Status			=	O10-Ed T-blad			ORDER INFORM	IATION			
component parts reverse numbered?		NI.				Dosage Form:	Oral Solid - Tablet		Init of Sale		What is the I	IDC colling	unit?	
co-licensed?		No No	Allergens Present					II	x Bottle		1 bottle of 30		unit:	
latex-free?		Yes	Allergens i resent				Triangle-shaped		Box/Carton		(Write-in, e.g		(Vials)	
preservative-free?		Yes				Product Shape:	mangio emapoa		Ampule		(**************************************	,	· viaio)	
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: '8'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					Product Imprint:			Vial Liquid Multi		If Yes, how I		ch package	type?
hospital scanning?		No	Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (ΓAA)?					Vial Power Multi			Inner/Carton	Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Au		Authorized Generic, other			ARMACY ORDER	/ BILL UNIT			
	AB					sec	ction fields are not applicable	Rec. sell unit to	customer?		Rx billing ur	it to pharma	cy:	
II. Generic Equivalent to What Bran	nd?:	Bystolic										Each		
		DDIIA GUDDI	V 0111111 05011DIEV 105					(Write-in, e.g. 1	Vial)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFO	RMATION							Milliliter		
Does supplier meet DSCSA definit	tion of manufactur	-ar2	Yes	_	GLN:	0331722000000			ITEM	AND PACKING IN	IEOPMATION			
Is product exempt from DSCSA?	lion of manufactur	err	No No	-	GLN.	0331722000000			II LW	AND I ACKING II	II OKWATION			
-					000			1		Dimar-1	one /IIC	to \	M-1-	0-1
If yes, select exemption: Other exemption - Write in:					GCP:			1	Weight Lbs.		ons (US msm Width	•	Volume (Cube)	Saleable # Pieces
					W					Depth	wiatn	Height	(Cube)	Pieces
le product reporteded			No									_		1
Is product repackaged?	avelusiva distribu	itor?	No No			iginal product purchas	ed	Item/Each:	0.05		1.5	3		
Is product sold by manufacturer's			No		direct from m	ifr?					1.5	3		
Is product sold by manufacturer's Has FDA granted waiver/exception	n/exemption for pr				direct from m			Box/Carton/Bur			1.5	3		
Is product sold by manufacturer's	n/exemption for pr		No		direct from m	ifr?		Box/Carton/Bur	ndle/	40.0				
Is product sold by manufacturer's Has FDA granted waiver/exception	n/exemption for pr	oduct?	No	NFORMATION	direct from m	ifr?		Box/Carton/Bur		10.2	7	4.8	0.14	24
Is product sold by manufacturer's Has FDA granted waiver/exception	n/exemption for pr	oduct?	No No	NFORMATION	direct from m	ifr?		Box/Carton/Bur	ndle/	10.2			0.14	24
Is product sold by manufacturer's Has FDA granted waiver/exception	n/exemption for pr n FDA.	oduct?	No No	NFORMATION	direct from m Provide source	ifr?		Box/Carton/Bur Inner Pack: Case:	ndle/	10.2			0.14	24
Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X Item/Each	n/exemption for pr n FDA.	oduct?	No No N AND HIBCC PRODUCT I	NFORMATION	direct from m Provide source	ofr? ce manufacturer for re	packaged product	Box/Carton/Bur Inner Pack: Case:	1.8	10.2	7	4.8		
Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	n/exemption for pr n FDA.	GTIN	No No N AND HIBCC PRODUCT I	NFORMATION	GTII	off? ce manufacturer for rep N-14 31722585309	packaged product	Box/Carton/Bur Inner Pack: Case:	ndle/	10.2	7	4.8	0.14 R USE ONL	
Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X term/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTING STATE OF THE	No No N AND HIBCC PRODUCT I	NFORMATION	GTII	off? ce manufacturer for rep	packaged product	Box/Carton/Bur Inner Pack: Case: Pallet:	1.8	10.2	7	4.8		
Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	n/exemption for pr n FDA.	GTIN	No No N AND HIBCC PRODUCT I	NFORMATION	GTII	off? ce manufacturer for rep N-14 31722585309	packaged product	Box/Carton/Bur Inner Pack: Case: Pallet:	1.8 COST INFORMATION		7 Vendor #:	4.8 VHOLESAL		
Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X term/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTIN	No No N AND HIBCC PRODUCT I	NFORMATION	GTII	off? ce manufacturer for rep N-14 31722585309	packaged product	Box/Carton/Bur Inner Pack: Case: Pallet:	1.8 COST INFORMATION		7 Vendor #: Whsl. Code	4.8 VHOLESALI		
Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X term/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTIN	No No N AND HIBCC PRODUCT I	NFORMATION	GTII	off? ce manufacturer for rep N-14 31722585309	packaged product	Box/Carton/Bur Inner Pack: Case: Pallet: Regular Cost Invoice Cost (W	1.8 COST INFORMATION		7 Vendor #:	4.8 VHOLESALI		
Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X term/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTIN	No No N AND HIBCC PRODUCT I	NFORMATION	GTII	off? ce manufacturer for rep N-14 31722585309	packaged product	Box/Carton/Bur Inner Pack: Case: Pallet:	1.8 COST INFORMATION		7 Vendor #: Whsl. Code	4.8 VHOLESALI		
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Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X term/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr n FDA.	GTIN	No No N AND HIBCC PRODUCT I		GTII 003	N-14 31722585309 31722585303	packaged product	Box/Carton/Bur Inner Pack: Case: Pallet: Regular Cost Invoice Cost (W As of date:	1.8 COST INFORMATION (AC) (\$)		7 Vendor #: Whsl. Code	4.8 VHOLESALI		



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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?	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 Inorganic Steroid/Androgen	Corrosive Oxidizer 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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class		Haza	rdous 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)	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?